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DEVELOPMENT OF A WORKPLACE RISK ADVISOR FOR HUMAN ENGINEERING DESIGN REVIEW OF SYSTEM MAINTENANCE

Cariold B. Harrah
Todd Harrah
Elizabeth T. Hewins
Carl Drews

Operational Technologies Corporation
4100 N. W. Loop 410, Suite 230
San Antonio, Texas 78229-4253

HUMAN RESOURCES DIRECTORATE
LOGISTICS RESEARCH DIVISION
2698 G Street
Wright-Patterson Air Force Base, Ohio 45433-7604

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Contract Monitor

BERTRAM W. CREAM, Chief
Logistics Research Division

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Cariold B. Harrah
Carl Drews
Todd Harrah
Elizabeth T. Hewins

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
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4100 N.W. Loop 410, Suite 230
San Antonio, Texas 78229-4253

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There is an increasing need to assess and manage workplace risk due to the presence of chemical hazards. Both strong regulatory requirements and the need to maximize worker productivity sustain this need. The lack of effective tools for handling the imprecise information frequently available for such assessments has prevented the development of comprehensive tools in the past. This study determined the feasibility for developing a Task-based Risk Assessment and Management (TRAM) System. As envisioned, TRAM would be a software system designed to provide industrial hygienists, human factors specialists and process engineers with a Windows-based graphical environment for assessing the health and safety risks posed by the use of hazardous chemicals. This would all occur in a three-dimensional graphical simulation environment. It was concluded that a feasible approach would utilize fuzzy logic, case-based reasoning, monte carlo simulation and queuing theory to support the underlying analysis. To use TRAM, the user would set up the simulation by specifying the industrial process and worker tasks in a flow charting environment, including workplace environmental parameters and chemicals of concern. Simulation and analysis could then occur ins several stages, including material balance, hazard identification, exposure analysis, computation of a risk index, and presentation of risk management strategies..

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LIST OF ACRONYMS

ACC	Air Contaminant Concentration
AFR	Air Force Regulation
ANSI	American National Standards Institute
APN	Abatement Priority Number
CAA	Clean Air Act
CEI	Cost Effectiveness Index
CSC	Computer Software Component
CSCI	Computer Software Configuration Item
CSU	Computer Software Unit
DBMS	Data Base Management System
DGMS	Data Generation Management System
DoD	Department of Defense
EP	Exposure Potential
EPA	Environmental Protection Agency
ETP	EcoToxicological Properties
FN	Fuzzy Number
GRI	General Risk Index
GUI	Graphical User Interface
HAZCOM	Hazard Communication
HHWQC	Human Health Water Quality Criteria
HIDES	Hazard Identification Expert System
HSDB	Hazardous Substances Data Bank
IARC	International Agency for Research on Cancer
IRIS	Integrated Risk Information System
LC_{50}	Lethal Concentration for 50 percent of test population
LD_{50}	Lethal Dose for 50 percent of test population
LOAEL	Lowest Observable Adverse Effect Level
MBMS	Model Base Management System
MED	Minimum Effective Dose
MF	Membership Function
MSDS	Material Safety Data Sheets
NAS	National Academy of Sciences
NIOSH	National Institute for Occupational Safety & Health
NLM	National Library of Medicine
NOAEL	No Observable Adverse Effect Level
NOEL	No Observed Effect Level
NTP	National Toxicology Program
ODS	Ozone Depleting Substance
OSHA	Occupational Safety and Health Administration
P^2	Pollution Prevention
PCP	PhysioChemical Properties
PEL	Permissible Exposure Level
PHA	Process Hazard Analysis
PSM	Process Safety Management
RAC	Risk Assessment Code
RCRA	Resource Conservation and Recovery Act

LIST OF ACRONYMS (CONCLUDED)

R&D	Research & Development
RfC	Reference Concentration
RfD	Reference Dose
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemicals
SAR	Structure-Activity Relationship
SBIR	Small Business Innovation Research
SBM	Sequential Box Model
STEL	Short-Term Exposure Level
TP	Toxicological Properties
TPQ	Threshold Planning Quantity
TQM	Total Quality Management
TRAM	Task-Based Risk Assessment and Management
TRI	Toxic Releases Inventory
TSCA	Toxic Substances Control Act
TWA	Time-Weighted-Average
UT, CCPCT	University of Tennessee, Center for Clean Products and Clean Technologies
WCT	Work Cycle Time
WMR	Worker Metabolic Rate

A. PROJECT OVERVIEW

There is an increasing need to assess and manage workplace risk due to the presence of chemical hazards. Both strong regulatory requirements and the need to maximize worker productivity sustain this need. The lack of effective tools for handling the imprecise information frequently available for such assessments has prevented the development of comprehensive tools in the past.

Federal agencies and private industry must meet the requirements of ever stricter environmental and occupational health and safety regulations. Individual occupational health and safety regulations effectively assist risk assessors and managers in achieving compliance with the control of a workplace hazard. However, when several regulatory requirements are imposed together, as dictated by a wide variety of workplace characteristics, risk assessment and management tasks increase significantly in scope, complexity, and duration. Add to this the uncertainties commonly found in chemical hazard assessments (e.g., lack of quality health hazard data and vagueness in exposure scenarios), and the problem is even further compounded. The net effect is the hindrance of comprehensive proactive planning strategies for assessing and managing workplace hazards in existing and planned facilities. The aim of this Phase I effort was to determine the feasibility of developing a software system to help accomplish the above tasks and assist with the needed complex decision-making.

The results of Phase I research efforts indicate feasibility for the development of a software system that would provide industrial hygienists, human factors specialists, and process engineers with a Windows-based graphical environment for assessing the health and safety risks posed by the use of hazardous chemicals. This could be a three-dimensional graphical simulation environment that provides the capability to (1) identify chemical health and safety hazards; (2) create, graphically, maintenance and manufacturing processes and facilities; (3) create and associate worker tasks with processes and facilities; (4) simulate the dynamic work environment; and (5) receive, from the system, analysis results on estimated exposures of workers to hazardous materials, estimates of overall risk in a work scenario, possible control strategies (subject to cost constraints), pollution prevention opportunities, regulatory implications, process efficiency and adequacy of facility with respect to worker risk and performance. OpTech has named this system the Task-Based Risk Assessment and Management (TRAM) System.

TRAM research, design, and development is an interdisciplinary effort, with significant overlap in the professional areas of occupational health, human factors, and computer science. Phase I efforts included an in-depth study of the state of the art in these disciplines, and determined the technology areas that must be further researched for the design and development of the TRAM system. They include the design, development, and implementation of reasoning systems, a hazard identification function, an exposure assessment function, a risk estimation function, the integration of system functional elements, and validation of the software system in accordance with acceptable industry practices.

To accommodate the imprecision in input information, OpTech examined the possibility of combining classical mathematical techniques (e.g., monte carlo simulation and queuing theory) with relatively recent innovative techniques (e.g., fuzzy logic and fuzzy case-based reasoning).

OpTech also examined the possibility of creating a graphical analysis environment that would permit increased visualization of the interaction among variables and provide an extension to the tool for performing "what-if" exercises.

In addition to technical feasibility, OpTech considered the potential for practical use of a tool such as TRAM. Based on the commercialization potential investigation to date, an innovative, user-friendly TRAM system could have wide application in the private sector and the Department of Defense (DoD). It would contribute to good workplace facility design practice and improve assessments of existing industrial operations, thereby helping users meet the intent as well as the letter of the law.

This Final Scientific and Technical Report (Final Report), will report on the specific areas of Phase I investigation that have led OpTech to the conclusion that further design and development of the TRAM system is technically feasible as well commercially viable. The majority of Phase I activities are presented in the following section (Phase I Investigation Summary). Section C, Future Work, summarizes the direction suggested for the continued research, design, development, test and evaluation, and commercialization of the TRAM system. The bibliography compiled in support of Phase I research activities is presented in Section D.

B. PHASE I INVESTIGATION SUMMARY

Eight primary technical objectives were identified in the Phase I proposal. Specifically, the eight Phase I technical objectives were as follows.

(1) To identify previous research and development (R&D) work that has value to add in the conceptualization and development of a design review tool to aid in the evaluation of system maintenance and support environments for the identification and assessment of unacceptable health and safety risks to which the worker is exposed.

(2) To review existing human engineering analysis technologies used to support design and maintenance activity evaluations. Of particular interest is to identify those technologies which lend themselves to risk assessment and management capabilities within the context of human engineering evaluations.

(3) To assess the availability of standards, guidelines, and health effects data for physical and chemical agents. The identification of standards and guidelines or the development of methods to estimate health effects data is a crucial aspect of developing a robust occupational risk assessment model for use in decision-making contexts.

(4) To develop and demonstrate the feasibility of the technical and analytical approaches chosen to perform their assigned functions within generalized models for risk assessment and management. The generalized paradigm of choice in this research was formalized by the National Academy of Sciences (NAS) and views the risk assessment process as consisting of four components: hazard identification, dose response data, exposure assessment, and risk characterization (U.S. Environmental Protection Agency, 1992b).

(5) To determine an overall best feasible approach to develop a workplace risk assessment and management evaluation tool for maintenance processes. In view of the encouraging current state of the art in tools for assisting designers in performing human engineering analysis, it will be our objective to interface with the most promising analysis tools.

The work summarized in the following sections, addresses these technical objectives and indicates feasibility. Furthermore, it provides the baseline research for progressively moving from formalizing the conceptual framework for the design to conducting the system development, test, and evaluation.

B.1. Development of the Framework for Design

The major elements fixing the basic framework for TRAM design are the strong occupational health **regulatory requirements**, the key underlying **risk assessment process** needed to assess compliance, and the user's **decision support needs** for effective task-based risk management. A comprehensive **literature search** was an essential Phase I task which allowed OpTech researchers to clearly and concisely define framework elements.

B.1.1. Literature Search

Literature Search Methodology. Several preliminary literature searches were conducted during Phase I. Searches were conducted for the proposal writing process, in preparation for starting the project, at the start of the project, and throughout Phase I. These literature searches covered a wide range of applicable topics and were completed in several phases as the project focus matured. As with all research projects, the literature searches reflected a movement from general concepts to more specific concepts as the research is refined and revised. Many of the initial searches were conducted to provide basic background knowledge and to identify the core research journals and articles. Once the basic body of core research was identified in these initial searches, the topics were refined and searches were run again. Once key articles and key researchers were identified, more refined searches were conducted. The initial body of literature suggested further topics and further concepts that were then searched. At the close of this Phase I effort, a large body of literature had been identified, collected, and arranged for the research team. The bibliography is located in Section D of this report.

Topics Researched. As mentioned, several topics have been searched, refined, and re-searched over the course of the last several months in preparation for and in support of this research project. Below is a brief description of the topics searched.

1. Genesis of workplace exposure standards
2. Trends in workplace exposure standards
3. Environmental health monitoring and trends
4. Occupational exposure and trends in monitoring for exposure
5. Process design and environmental health and safety considerations
6. Occupational exposure sources, such as noise, lasers, microwave radiation, electromagnetic devices, chemicals, etc.
7. Occupational diseases
8. Occupational risks
9. Fuzzy logic and risk analysis
10. Neural nets and risk analysis
11. Case-based and evidential reasoning

Each of these broad topics was refined and focused throughout the search process. Obviously, there was overlap in topics and all duplicate citations were eliminated.

Databases Searched. Several databases were identified as relevant to the research. During future efforts, these databases will be routinely searched to monitor the literature of the above eleven areas, as well as other relevant areas. Below is a brief description of the databases identified as relevant

1. **MEDLINE**--Produced by the National Library of Medicine, MEDLINE provides coverage of the world's biomedical literature. MEDLINE indexes over 6,000 international biomedical journals. MEDLINE is the online version of the printed index, *Index Medicus*, as well as the *International*

Nursing Index and the *Index to Dental Literature*. MEDLINE, which is updated weekly, covers the literature from 1966 to the present for a total of over 6 million citations. MEDLINE is searched using the GRATEFUL MED search software. The current file, covering the period 1989 to the present, was searched in Phase I and will be searched rountinely during any follow on work.

2. **INSPEC**--This database is the online version of three printed indexes: *Physics Abstracts, Electrical and Electronics Abstracts*, and *Computer and Control Abstracts*. It includes citations from 1969 to the present, covering international literature. INSPEC is especially effective for searching fuzzy logic and neural net concepts but is also effective for process design and engineering issues.

3. **EI Compendex Plus**--This database is the online version of *The Engineering Index*, which provides citations to the world's literature on engineering and technology. It includes more than 4,500 journals and government reports. It covers such topics as civil, environmental, geological, electrical, automotive, nuclear, and aerospace engineering, computers, and robotics. It is updated weekly and covers the literature from 1970 to the present. Compendex, like INSPEC, is especially effective for searching fuzzy logic and neural nets. Additionally, it is very effective for searching engineering issues, such as process design and industrial hygiene.

4. **MathSci**--This database contains reviews and abstracts of the world's literature on mathematics, computer science, statistics, econometrics, and applications in areas such as physics, engineering, biology and information systems. It corresponds to seven different printed indexes. While it is especially effective for searching the concepts of fuzzy logic and neural nets, it is also effective for searching the other concepts, such as process design and occupational exposure.

5. **EMBASE**--Excerpta Medica is one of the leading sources for searching the world's biomedical literature found in over 3,500 international biomedical and pharmacological journals. It is updated weekly and covers the literature from 1974 to the present. Like MEDLINE, EMBASE is especially useful for searching the concepts of occupational exposure and occupational diseases.

6. **Chemical Engineering and Biotechnology Abstracts**--Produced by the Royal Society of Chemistry, this database provides information on industrial practice and theoretical chemical engineering. It is updated monthly and covers the literature from 1971 to the present. This database is effective for searching the literature on occupational exposure to chemicals and chemical mixtures.

7. **Pollution Abstracts**--This database is an excellent source of information on all aspects of pollution including air pollution, environmental quality, noise pollution, pesticides, radiation, solid wastes, water pollution, and so forth. It is especially effective for searching the literature on exposure to specific hazards, such as noise, radiation, electromagnetic devices, and the like. The database is updated monthly and covers the period 1970 to the present.

8. **Enviroline**--This database provides coverage of more than 5,000 primary international journals and secondary publications covering all aspects of the environment. Literature includes journals, books, government documents, industry reports, conference proceedings, newspaper articles, and monographs. It is updated monthly and covers the literature from 1971 to the present.

9. **Occupational Safety and Health (NIOSHTIC™)**--This database is produced by the Technical Information Branch of the National Institute for Occupational Safety and Health (NIOSH). It provides citations to more than 70,000 monographs and technical reports. This database is helpful in identifying NIOSH research on occupational exposure and occupational safety and health. It is updated quarterly and covers the period 1973 to the present.

In addition to the actual literature searches that were conducted, the research team also identified other sources of information that potentially may be used by the research team in follow-on research. One very important type of information for this research project is factual information about chemicals, such as the information found on the Material Safety Data Sheets (MSDSs). The research team uses a compact-disc-based information source for this type of information. The compact-disc information source is **TOMES Plus**, produced by Micromedex, Inc. **TOMES Plus** comprises several databases that provide health and safety information for chemicals. TOMES Plus includes the following chemical databases:

1. **IRIS**--The Integrated Risk Information System (IRIS), prepared and maintained by the U.S. Environmental Protection Agency (EPA), is an electronic database containing health risk and U.S. EPA regulatory information on specific chemicals. IRIS was developed for EPA staff in response to a growing demand for consistent risk information on chemical substances for use in decision-making and regulatory activities. The heart of the IRIS system is its collection of computer files covering individual chemicals. These chemical files contain descriptive and numerical information in the following categories:

   -- Oral and inhalation reference doses (RfDs) for chronic noncarcinogenic health effects

   -- Oral and inhalation slope factors and unit risks for chronic exposures to carcinogens

   -- Drinking water health advisories from U.S. EPA's Office of Drinking Water

   -- U.S. EPA regulatory action summaries

   -- Supplementary data on acute health hazards and physical/chemical properties

   The information in IRIS is intended for use in protecting public health through risk assessment and risk management. Risk assessment has been defined as "the characterization of the potential adverse health effects of human exposures to environmental hazards." In a risk assessment, the extent to which a group of people has been or may be exposed to a certain chemical is determined, and the extent of exposure is then considered in relation to the kind and degree of hazard posed by the chemical, thereby permitting an estimate to be made of the present or potential health risk to the group of people involved. IRIS is a tool which provides hazard identification and dose-response assessment information but does not provide situational information on individual instances of exposure. Combined with specific exposure information, the data in IRIS can be used for characterization of the public health risks of a given chemical in a given situation, which can then lead to a risk management decision designed to protect public health.

2. **HSDB**--The Hazardous Substances Databank (HSDB) is produced by the National Library of Medicine. It is a factual database focusing on the toxicology of 4500 potentially hazardous

chemicals. HSDB is fully referenced and peer-reviewed by a Scientific Review Panel. HSDB includes information on:

--Substance information
--Manufacturing/use information
--Chemical and physical properties
--Pharmacology
--Environmental fate/exposure potential
--Exposure standards and regulations
--Monitoring and analysis methods
--References

3. **RTECS**--Registry of Toxic Effects of Chemicals (RTECS) is produced by NIOSH. It contains both acute and chronic toxic effects data on more than 110,000 chemicals. This database reports results of mandatory testing data on chemicals produced for commercial purposes. It is not peer reviewed. This database includes information on:

--Substance identification
--Toxicity/biomedical effects
--Toxicology and carcinogenicity review
--Exposure standards and regulations

4. **NIOSH Pocket Guide to Chemical Hazards**--The Pocket Guide is intended as a source of general industrial hygiene information for workers, employers, and occupational health professionals. It presents key information and data in a tabular form for 400 chemicals or substance groupings that are found in the work environment and have existing Occupational Stafety and Health Administration (OSHA) regulations.

Post-Processing Activities. After the literature searches were completed, the output was downloaded into a specialized bibliographic database system used to locally search the literature and produce bibliographies. This database software, **Pro-Cite**, is a specialty database used to manage large bibliographic collections. It allows for the creation of bibliographies in specific formats. Bibliographies were produced and passed on to the research team for evaluation. Once relevant citations were identified, attempts were made to locate copies of the articles, books, proceedings, and so forth. To this end, local libraries were utilized (including the libraries at the University of Texas at Austin) and a small research collection of these articles, proceedings, and the like was made available for researchers. In future work, searches will be conducted using the bibliographic and factual databases above and the research collection will grow as necessary.

B.1.2. Regulatory Drivers

Regulatory criteria are important aspects of the design framework. The largest body of regulations that must be addressed in a work environment are promulgated through the OSHA. There are several OSHA criteria for regulating chemical specific exposures, and most use a time-weighted-average (TWA) exposure approach. OSHA's TWA criteria include the Permissible Exposure Level (PEL) and the Short-Term Exposure Level (STEL). PEL is TWA exposure over an eight-hour period (a full work day); STEL is a thirty-minute average. Other criteria include a ceiling limit (a maximum exposure level independent of time) and a skin designation for chemicals that have the potential to harm the skin (e.g., strong caustics) or are readily absorbed. In addition, OSHA has a more stringent set of standards on a set of hazardous air contaminants (29 CFR 1910.1000 - 1910.1500). For these contaminants,

OSHA demands that very specific risk control measures be satisfied. Another important standard is OSHA's Process Safety Management (PSM) of Highly Hazardous Chemicals (29 CFR 1910.119), which is built around a Process Hazard Analysis. The PSM objective is to prevent unwanted releases of hazardous chemicals, especially into locations that would expose workers and others to serious hazards. This standard will have significant health and safety management implications for many companies in the upcoming years (NUS Training Corporation, n.d.). TRAM would address these and additional OSHA concerns which focus on chemical health and safety.

The boundaries between environmental and occupational law and policy are often blurred. Policy derived for environmental purposes often places requirements on workplace operations and facilities. A prime example is the Resource Conservation and Recovery Act (RCRA). RCRA, through a strict permitting process, regulates the management of hazardous wastes to include storage, treatment, and disposal. Such requirements obviously affect the definition of tasks associated with industrial processes, whether in private industry or government facilities. An interface to environmental regulations that strongly influence, even initiate, change in the workplace, would be a necessary part of a realistic chemical risk assessment tool for the workplace.

In addition to the mainstream environmental compliance regulations and policies, those developed from the pollution prevention (P^2) movement heavily influence activities in the workplace. P^2 is the use of substitute materials, process changes, and work practice changes to reduce or eliminate the creation of pollutants (Battelle, 1992). For instance, the phase-out of the use of ozone depleting substances (ODSs), as specified in Title 6 of the Clean Air Act (CAA), is focused at ending the depletion of the earth's ozone layer. However, this cannot be accomplished without changing processes and work practices that currently utilize ODSs. Unfortunately, many ODSs were originally used because they were much less toxic or explosive than their non-ODS counterparts. The job of finding alternatives to ODSs has not been easy and continues to involve combinations of workplace alterations including material substitution, and process and facility changes. Another environmentally based effort affecting the workplace is the EPA initiative to reduce the use of 11 organic compounds and 6 inorganic compounds. This group is often referred to as the EPA 17 Targeted Chemicals. Due to the very real workplace influence of efforts (e.g., the ODS and EPA 17 elimination efforts), TRAM should contain functions for identifying P^2 opportunities and flagging actions which oppose P^2 philosophy and policy.

OSHA regulations, environmental regulations, and P^2 initiatives would be implemented in TRAM through the use of rule bases, case-based/evidential reasoning techniques, and internal databases containing the interpreted standards and policy. Through these features, TRAM could identify and present to the user, the relevant standard and policy considerations based on a postulated work scenario. The ability to perform this effectively and elegantly could be ensured by appropriately defining the bounds and interfaces to "workplace concerns." For instance, TRAM could contain knowledge about RCRA as it interfaces with the workplace, not the entire Act.

B.1.3. Risk Assessment Paradigm

The heart of the TRAM system utility would be the chemical risk assessment functions. The framework suggested to be used to organize and design risk assessment functionality is the risk assessment paradigm developed by NAS (National Research Council, 1983). It addresses qualitative and quantitative risk assessment, both of which should be implemented in TRAM. The four elements of the risk assessment process are defined as follows.

A. *Hazard Identification*. The process of determining whether exposure to an agent can cause an increase in the incidence of a health condition (e.g., cancer, birth defect, etc.). In other words, what kind of effect occurs given a sufficient dose.

B. *Dose Response*. The process of characterizing the relation between the dose of an agent administered or received and the incidence of an adverse health effect in exposed populations and estimating the incidence of the effect as a function of human exposure to the agent. Within TRAM, dose response is lumped into the hazard identification function for convenience.

C. *Exposure Assessment*. The process of measuring or estimating the intensity, frequency, and duration of human exposures to an agent currently present in the environment or of estimating hypothetical exposures that might arise from the release of new chemicals into the environment (e.g., determining likelihood of exposure).

D. *Risk Characterization*. The process of estimating the incidence of a health effect under the various conditions of human exposure described in exposure assessment.

The framework for risk assessment described in the NAS risk assessment paradigm should be used to implement the risk assessment function in TRAM. The exposure assessment function would be the most challenging function to be implemented in TRAM. This is in part due to the complexity of modeling and describing the way in which real occupational exposures occur. For example, a worker typically experiences time-varying exposures at a number of facility locations throughout a work day. Estimating a chemical exposure profile that captures both time-varying releases of hazardous agents as well as the time-varying location of the worker would be a complex design and development task. OpTech determined a three-point approach to minimize project risk associated with this segment of system development. The three points of this approach are as follows.

(1) Combine the best of existing air contaminant concentration models with fuzzy logic estimation techniques. Fuzzy logic is known for its ability to describe, in a model-free nature, the behavior of linear and nonlinear systems (Kosko, 1993).

(2) Utilize expert industrial hygiene, chemical, and biochemical engineers to assist in the technical design of the exposure assessment function.

(3) Initiate design and development of the exposure assessment function early in a future effort to allow time to address unexpected contingencies.

B.1.4. User Needs

Future work on TRAM design and development must also be based on thorough analysis and clear articulation of potential user's needs. As is often the case, especially for computer-based decision-support tools, precise definition of the user/customer base is difficult. This is not surprising considering the interdisciplinary nature of most real-world problems. For TRAM, OpTech defined potential users as process engineers, industrial hygienists, and human factors specialists. The professional interest areas of industrial hygiene and human factors have considerable overlap with both concerned about performance in the presence of hazardous chemicals, including the effects of the chemicals themselves as well as any protective control measures. However, their perspectives are different. Industrial hygiene typically places more emphasis on the measurement, analysis, and management of the chemical stressor against some health or safety criteria (Organization Resources Counselors, Inc., 1992). On the other hand, human factors emphasizes the preservation or

enhancement of physical and mental performance, which can include the effects of hazardous chemicals and the corresponding protective measures (Mason & Johnson, 1987).

In Phase I, OpTech researchers conducted potential user interviews with an industrial hygienist, a chemical/process engineer, and a human factors engineer to get an initial feel for the value these real-world users would place on a software system that performs the functions considered for TRAM. The results were encouraging. Frequent comments included (1) the suggestion to design TRAM to be process and worker task-oriented, (2) to ensure that TRAM addresses specific analyses required by law (e.g., OSHA's Process Hazard Analysis), and (3) to develop TRAM so that "what-ifs" can be performed as painlessly and efficiently as possible.

OpTech would continue to focus on these three potential user group needs in future work. In particular, rapid prototyping would be utilized to/ capture concepts in TRAM and present them to potential users for evaluation and comment. Comments would be evaluated and, when appropriate, TRAM design would be altered to accommodate these comments. This approach would help ensure that the majority of practical user needs would be supported by the TRAM system.

B.2. Reasoning Systems

Two emerging analysis techniques that would be reviewed and implemented in TRAM to handle vagueness and uncertainty, and to capture past experiences of experts in the areas of risk assessment and management are presented below.

B.2.1. Fuzzy and Neuro-Fuzzy Systems

B.2.1.1. Fuzzy Logic Background

Fuzzy logic is the foundation of a relatively new engineering design approach that can be applied to a broad spectrum of systems. It is a generalization of bilevel logic that allows for partial truth and partial falsehood. As an analytical technique, fuzzy logic is not new. It was created by Lofti Zadeh, at the time a professor of Electrical Engineering at the University of California, Berkeley, in the mid-1960s (Rasiowa, 1992).

To date, fuzzy logic has been overwhelmingly applied in the area of control systems (e.g., brake systems, subway systems, temperature control systems, etc.). In fact, fuzzy logic has been used so exclusively as a control mechanism (i.e., minimizing a system error) that it has become "typecast" as a non-classical control theory tool. At the 1994 Fuzzy Logic Conference in San Diego, nearly 60 percent of the papers presented focused on a specific control application. The other 40 percent were papers on fuzzy logic fundamentals, implementation methodology, development tools, and adaptive fuzzy systems. However, most of these topics used a control problem to make their point or demonstrate their tool or method. Non-control applications were few and far between (maybe 10 percent of the conference). The reason control theory has been the early recipient of fuzzy logic may be inconsequential. It's likely that the explanation is as simple as, "there had to be a first application or starting point" just as physics was almost exclusively the first application of differential calculus. We are all aware of how differential calculus permeates practically every scientific, engineering and economic analysis method used today. This is because of the fundamental principle underlying differential calculus (i.e., rates of change). Fuzzy logic too is built upon a fundamental principle (partial truths and falsehoods) that will allow it to permeate yet unthought of problem domains. OpTech believes that **risk assessment is one problem area that will be effectively modeled through fuzzy logic**. The remainder of this section describes the fundamentals of a couple of current fuzzy logic techniques reviewed during Phase I research.

B.2.1.2. Anatomy of a Fuzzy Logic System

Both man-made and natural systems are far from linear in nature. In fact, nonlinearity is the basic rule of system behavior. However, when nonlinear systems gain a degree of complexity, they become almost impossible to model unless some simplifying assumptions are made. Usually, the assumption is that nonlinear systems can be modeled as linear or piece-wise linear systems. Sometimes this works quite well, sometimes well-enough, but for a great many systems the modeling becomes too complex even with simplifying assumptions. This is where fuzzy logic has been demonstrated to perform well. Fuzzy logic supports development of a model-free approach to describing system behavior regardless of the degree of complexity of the system (second and even third order). The requirements for designing a fuzzy logic system include knowing the inputs to the system, the desired outputs, and the relationship between inputs and outputs. The relationships can be described linguistically (e.g., for a chemical used in a degreasing operation: If VAPOR PRESSURE is HIGH and RESPIRATORY IRRITATANT is VERY STRONG then VAPOR CONTAINMENT is VERY HIGH). Fuzzy logic systems, in general, tend to be more intuitive to develop and usually are completed in less time than classical mathematical modeling. Still, there is a formal mathematical process associated with a fuzzy-based system. Normally, some variation of the logic illustrated in Figure 1 is implemented (Brubaker, 1994).

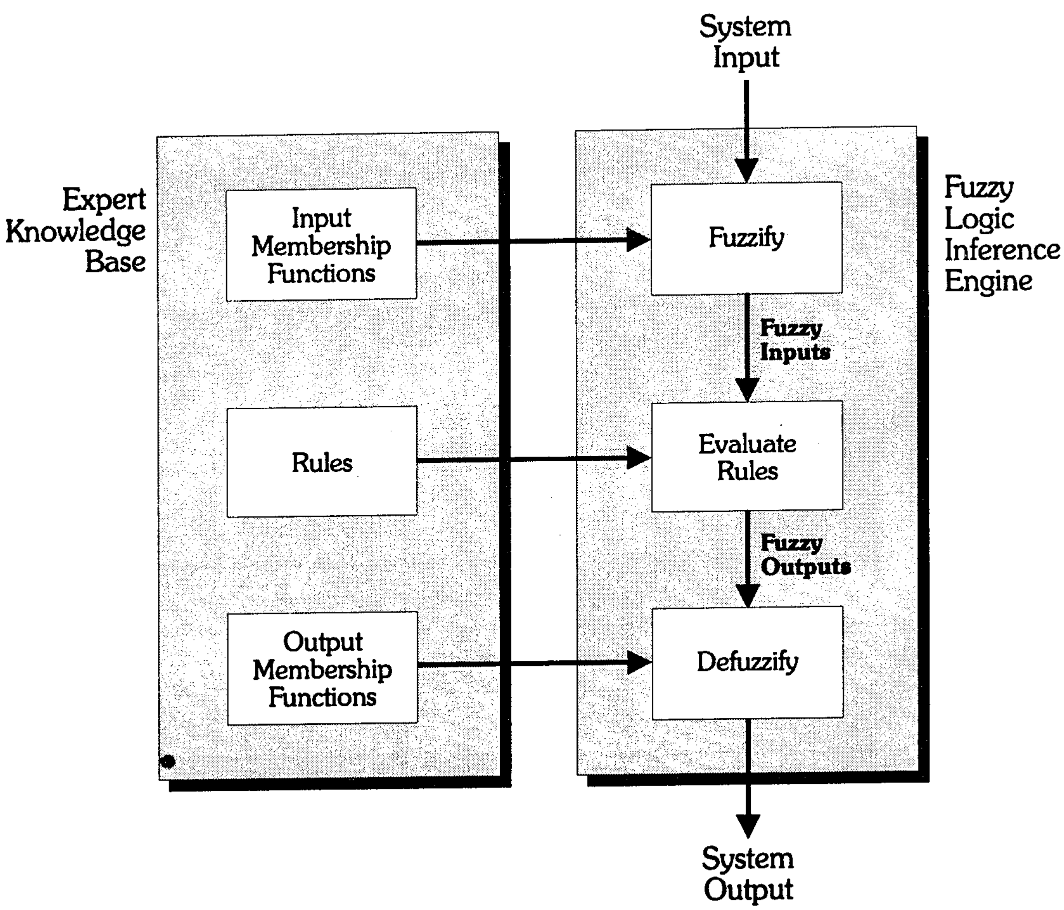


Figure 1. Block Diagram of a Fuzzy Logic System

The Knowledge Base. The Expert Knowledge base is made up of membership functions (MFs) and rules. An MF is a mapping between the universe of discourse (X-axis) and the grade space (Y-axis). The universe of discourse is the range of possible values for the system inputs or system outputs. A typical grade space value ranges from 0 to 1 and is called a degree (strength) of membership.

Figure 2 shows a set of five MFs ranging from -N to +N. Linguistic labels are used by the rules to reference the MFs. The MF labels in Figure 2 are VL (very low), L (low), M (moderate), H (high), and VH (very high). The MFs are triangular in Figure 2, but not by necessity. They could take on any form (e.g., a bell-shaped curve, trapezoid, spikes, or some other shape).

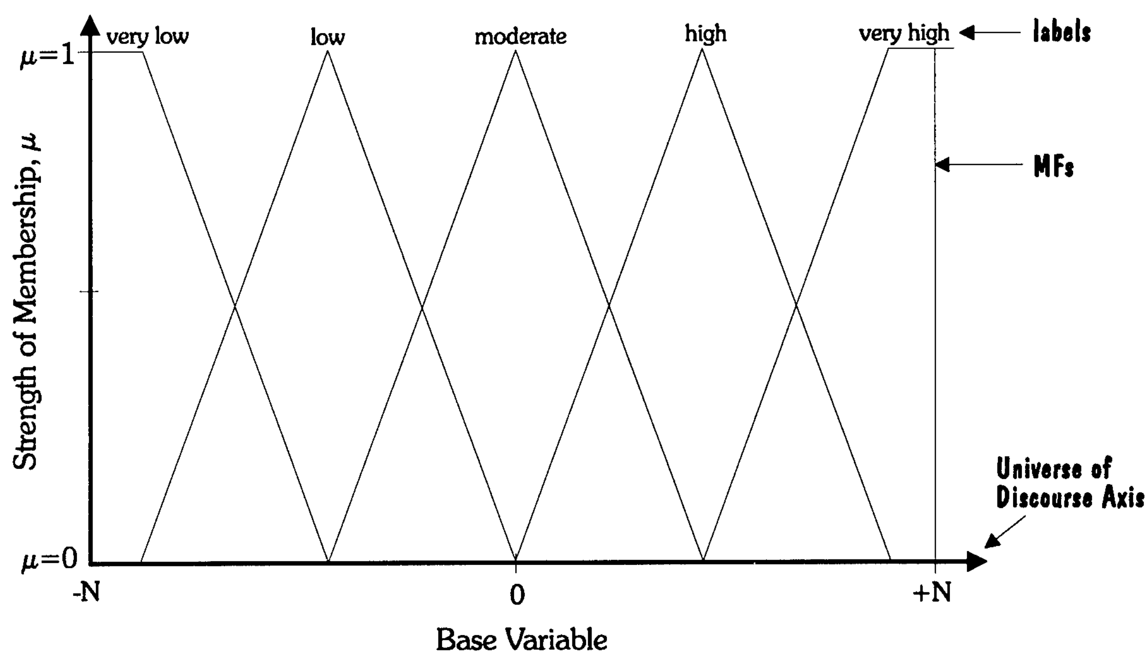


Figure 2. Fuzzy Set with Five Membership Functions

Rules are statements expressing a relation among system inputs and system outputs. Individual rules represent parts of the solution to the problem. All rules determined together represent the final solution. A sample rule for describing the behavior of an output, output1, for two input variables, input1 and input2, would be:

If input1 **is** VL **and** input2 **is** "very hot" **Then** output1 **is** "moderate";

where VL is taken from the MF defined in Figure 2. The descriptors "very hot" and "moderate" would have come from their own respective MFs. The "if" phrase of the rule is called the antecedent, and the "then" part of the rule is the consequent.

The knowledge base comprises the application-specific information in the fuzzy logic system. In a fuzzy system, the knowledge base is stored as data structures in memory. The MFs and rules are provided as part of the design process by an expert on the system or problem space. There is no limit to the number of system inputs, system outputs, MFs, or rules, but the total number of rules is proportional to the total number of input MFs.

The Fuzzy Logic Inference Engine. The fuzzy logic inference engine performs three main functions: fuzzification, rule evaluation, and defuzzification (Brubaker, 1994). These three steps can be described using, as an example, work cycle time (WCT). WCT is the length of time a worker can stay at his/her post performing required tasks before having to leave or take a break in order to prevent a chemical PEL from being exceeded as calculated by the TWA exposure concentration. For example, the system inputs might be the air contaminant concentration (ACC), with a range of 0 to 1000 mg/m3, and worker metabolic rate (WMR), with a range of 75 to 750 Kcal/hr. In this simple example, we are relating WMR to respiratory rate which, when increased, would cause increased absorption of the air contaminant into the worker's body.

Fuzzification. Fuzzification converts the system inputs into fuzzy inputs by finding a grade of membership for all membership functions (Brubaker, 1994). Figures 3(a) and 3(b) show the MFs for the two system inputs (WMR and ACC) and illustrate the fuzzification process for input values of WMR=500 Kcal/hr and ACC=100 mg/m3, shown on the axis. The grade of membership is the grade value at the intersection the system input value makes with a membership function. In Figure 3(a), for ACC, this yields a fuzzy input value of 0.80 for MF high and 0.35 for MF very high, while the other MFs will have a membership of zero. Likewise, for Figure 3(b) WMR, a fuzzy input value of 0.60 for MF high and 0.40 for MF moderate are obtained.

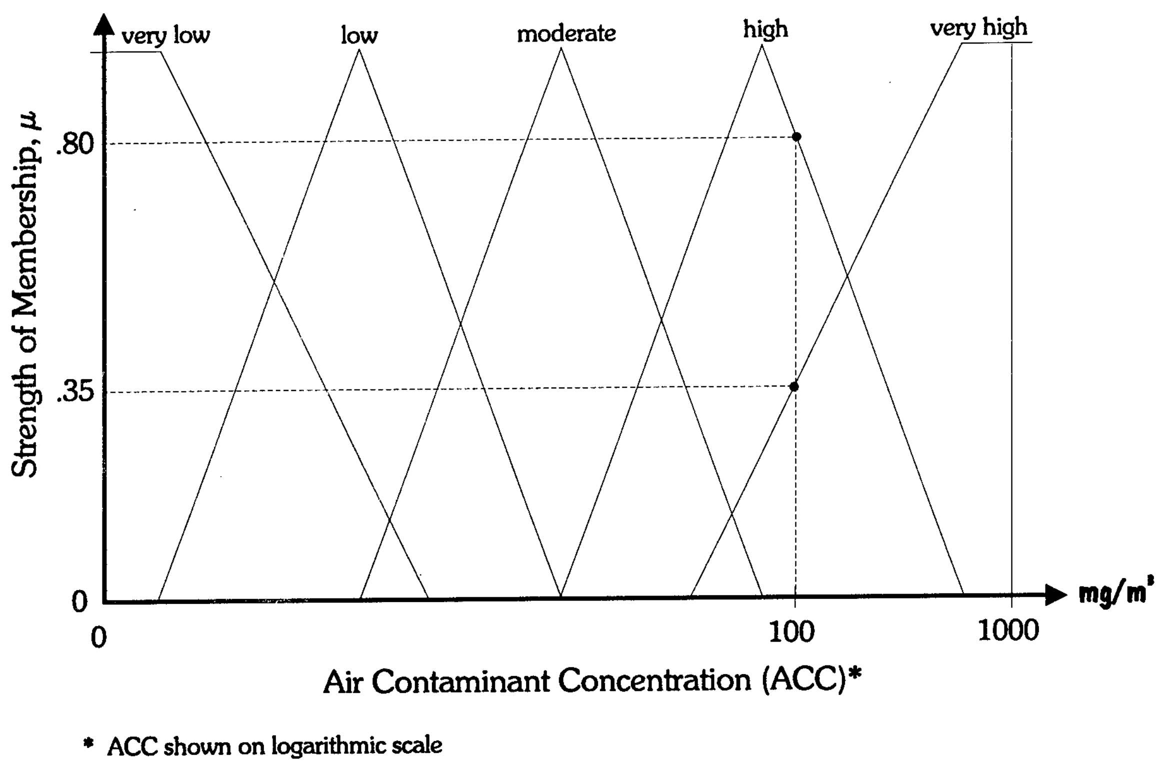


Figure 3(a). Input Membership Function and Fuzzification Step (ACC)

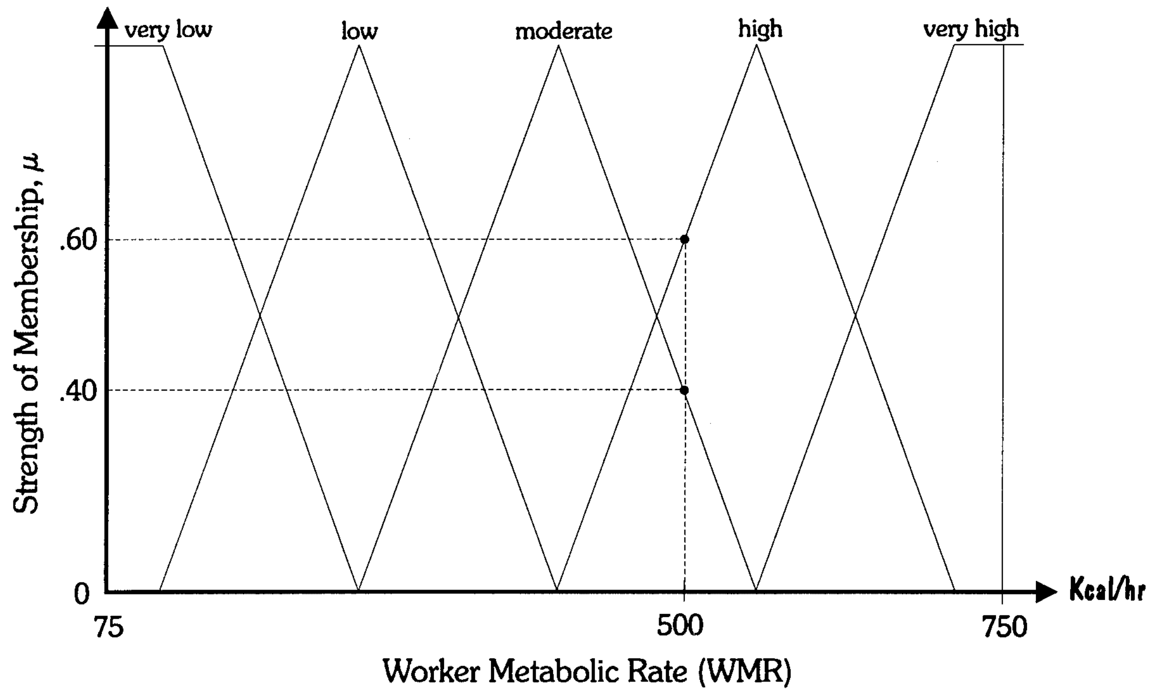


Figure 3(b). Input Membership Function and Fuzzification Step (WMR)

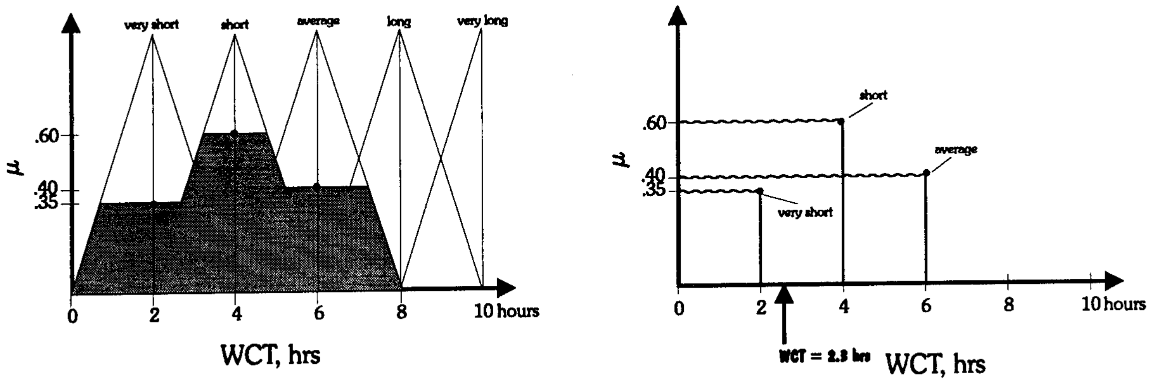
Rule Evaluation. Rule evaluation takes the inputs from the fuzzification step and the rules from the knowledge base and calculates fuzzy outputs (Brubaker, 1994). Table 1 lists some of the rules for the WCT estimator. Next to each membership label in the antecedents are the corresponding fuzzy inputs obtained in the fuzzification step. Although there are several inference methods, the most common is known as the MIN-MAX inference. In MIN-MAX inference, the minimum of the antecedents in each rule is considered the rule strength for that rule and is assigned to the consequent rule. For example, the first rule in Table 1 has a rule strength of 0.60 because this is the minimum of the fuzzy inputs in its antecedent (0.60 and 0.80). If more than one fuzzy rule recommends the same fuzzy output, the rule that is most true will dominate. This is implemented by taking the maximum of these rule strengths and assigning the value to the fuzzy output. For example, the first and fourth rules in Table 1 have MF "short" in their consequent so the maximum of their rule strengths (.60 and .35) is applied to output MF "short" (Figure 4(a)).

Table 1. Fuzzy Logic Rules and MIN-MAX Inference

Rule			Strength
If ACC is high (0.80)	and WMR is high (0.60)	then WCT is short	0.60
If ACC is very high (0.35)	and WMR is high (0.60)	then WCT is very short	0.35
If ACC is high (0.80)	and WMR is moderate (0.40)	then WCT is average	0.40
If ACC is very high (0.35)	and WMR is moderate (0.40)	then WCT is short	0.35

Defuzzification. Finally, the defuzzification process converts the fuzzy outputs from the rule evaluation step into system outputs (Brubaker, 1994). Just as there are several rule evaluation methods, there are also various defuzzification methods. A common defuzzification method is called *center of*

gravity or *centroid* defuzzification. The fuzzy outputs obtained in the inference step are used to truncate the corresponding output membership function at the appropriate truth value, as shown in Figure 4(a). Then the center of gravity of the resulting fuzzy sets is found, which is equivalent to finding the balance point of the resulting membership functions (shown in Figure 4(b) with an arrow).



(a) Output MFs

(b) Defuzzification Step

Figure 4. Output MFs and Defuzzification Step

Singletons are often used for embedded control applications because the defuzzification step involves the following simple equation:

$$Centroid = \frac{\sum_{All(x)} u(x)x}{\sum_{All(x)} u(x)}$$

where u(x) is the fuzzy output value for the universe of discourse value x. For example, based on Figure 4(b) and using the equation above, the output becomes:

$$Output = \frac{0.60(40\%) + 0.35(20\%) + 0.40(60\%)}{0.60 + 0.35 + 0.40} \approx 23\%$$

This might imply that a worker with a metabolic rate of 500 K/cal, exposed to 100 mg/m^3, should work a maximum of 2.3 hours at that particular work station, based on a user-defined 10-hour work day. This simple example was used only to demonstrate a process. In reality, several other factors would have to be considered to determine WCT (e.g., the toxicity of the chemical).

Once the three steps of fuzzification, rule evaluation, and defuzzification are finished, the process can be repeated for varying states of the different variables. In a control process, the system would likely repeat specified increments of time in order to minimize output error. In an estimation problem such as within WCT, the process might be repeated with time as the ACC varies. Then, over a given period, an average WCT could be developed for segments of a maintenance process.

B.2.1.3. Fuzzy Ranking

A variation of the general fuzzy logic process is used to rank potential alternatives in multi-criteria decision-making problems. TRAM would have to assist the user in many of these types of problems. During Phase I, the following algorithm for ranking in a fuzzy decision-making process was determined to be sufficient for use in TRAM. The algorithm was developed in two journal articles by Tseng and Klein 1988; 1989.

Ranking fuzzy numbers has been a concern in fuzzy decision-making since its inception. The ranking of two fuzzy numbers has received considerable attention; however, little attention has been applied to the ranking of more than two fuzzy numbers. This algorithm addresses the ranking of N fuzzy numbers. This is particularly relevant for TRAM, which will require the ranking of multiple fuzzy numbers.

To highlight some of the more outstanding features of the fuzzy ranking method, consider the following simple case. Two chemicals, A and B, are being evaluated for exposure and absorption potential via ambient air around the worker. Several parameters for each chemical have been identified (e.g., vapor pressure, molecular weight, octanol-water partition coefficient, etc.). Further, for each chemical, their respective parameters have been assigned values and aggregated through fuzzy methods so that each chemical's overall exposure potential (EP) is now represented by a single fuzzy number (FN). These two FNs might be resting on a real line as shown in Figure 5(a).

The objective is to determine which FN represents the highest index of EP. Assume that moving to the right indicates increasing EP. There are two notions associated with the FNs in Figure 5(a): indifference and dominance. The area of overlap is termed "indifference." This is shown in Figure 5(b). The areas of nonoverlap express the "dominance" of A over B or B over A. There are rules that apply which dictate whether a nonoverlap area represents A dominating B or B dominating A. For example, A dominates B if for *nonoverlapping* FNs:

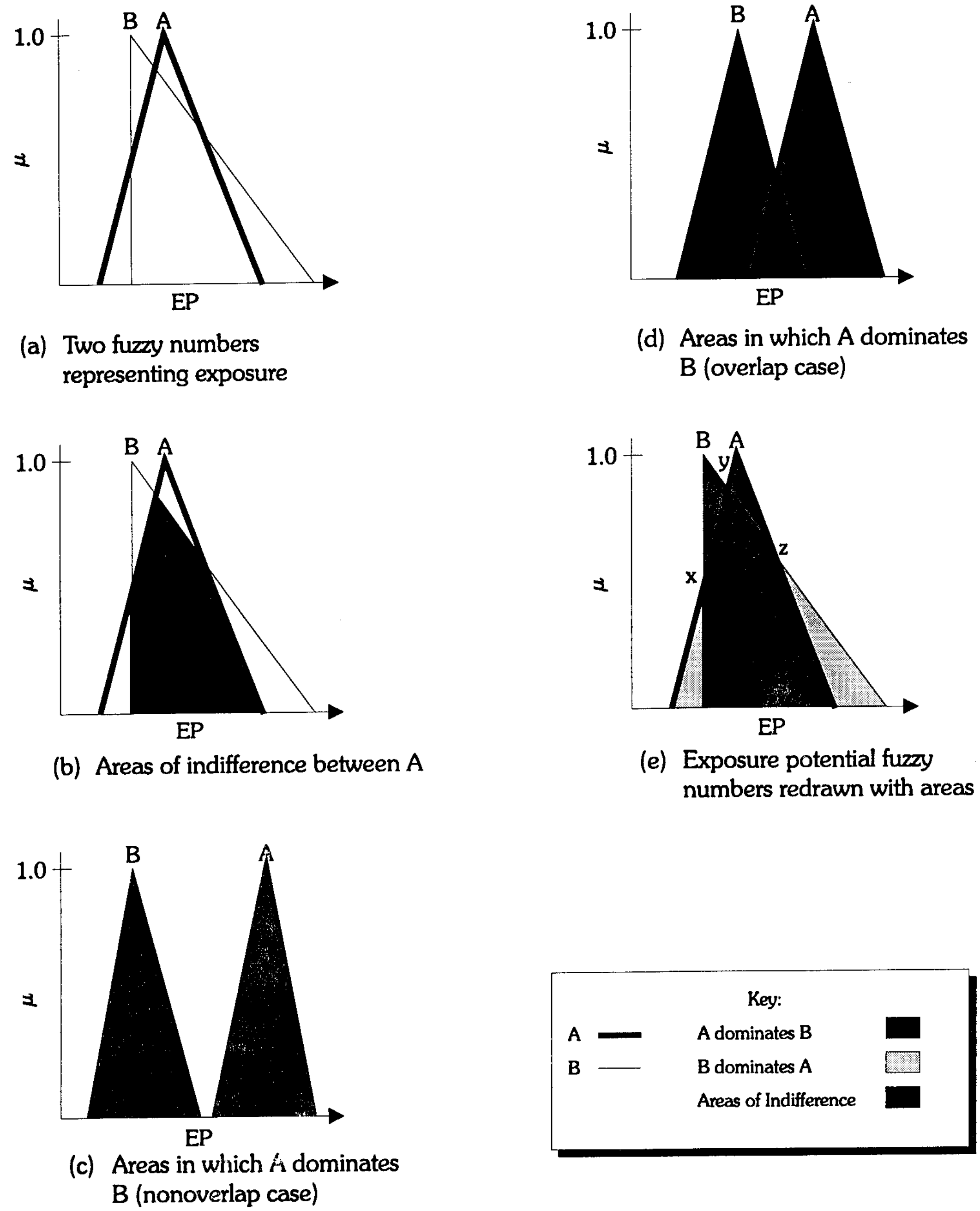
FN A is on the right-hand side of B,
FN B is on the left-hand side of A,

as shown in Figure 5(c), or, for *overlapping* FNs:

if the area belongs to A and is on the right-hand side of the overlap area
if the area belongs to B and is on the left-hand side of the overlap area

as shown in Figure 5(d).

The triangles for the EP problem are redrawn in Figure 5(e) with the indifferent and dominant areas shaded. A dominates B, can be interpreted as the degree to which the EP for chemical A is higher than the EP for chemical B. The interval of domination is generally easy to see through visual inspection. However, finding this interval for numerical implementation can become difficult, particularly for nonconvex or nonpiecewise linear functions. In this example, the two triangles are piecewise linear. A computational method for finding the areas of dominance is called the Hamming Distance D(A,B).



(a) Two fuzzy numbers representing exposure

(b) Areas of indifference between A

(c) Areas in which A dominates B (nonoverlap case)

(d) Areas in which A dominates B (overlap case)

(e) Exposure potential fuzzy numbers redrawn with areas

Figure 5. Illustration of Fuzzy Ranking

The Hamming Distance between two FNs for the arrangement depicted in Figure 6(e) is defined:

$$D(A,B) = \int_x^y |\mu_a(EP) - \mu_b(EP)| dEP + \int_y^z |\mu_a(EP) - \mu_b(EP)| dEP$$

where,

D(A,B) means the dominance of A over B.

For the sample EP problem, the Hamming Distance equation determines that D(A,B) is equal to D(0.52, 0.48) or A is dominant over B by a degree of 0.52. This dominance can be expressed as A>B. With this intermediate computation complete, the risk assessment analysis could proceed (e.g., by relating the chemicals ranked by EP with each of their ranked toxicity profiles).

The above case is a simple one in that the FNs were piecewise linear functions. In addition, only two FNs were being compared. In TRAM, it would be necessary to rank many fuzzy numbers (e.g., many candidate chemicals or mixtures). A method of paired comparisons can be used to accomplish this objective. The method works as follows. In general, if there are N FNs, N(N-1)/2 pairs are needed to be used for the ranking order. For example, suppose there are five numbers to be ranked A = (A1, A2, A3, A4, A5) and the pairwise comparisons determine the following dominance relationships (with all the "is preferred to" signs pointing to the right):

A1>A2	**A1>A3**	**A1>A4**	**A1>A5**
	A2>A3	**A2>A4**	**A2>A5**
			A3>A5
	A4>A3		**A4>A5**

Then, with five FNs, the most preferred one (or the one with the highest EP in our sample case) should appear on the left-hand side of the "is preferred to" sign four times. Above, the FN that satisfies this requirement is A1. Logically, we next look for the FN with three appearances on left, then two, and finally one. The resulting priority list is then as follows,

A1> A2> A4> A3> A5

The technique is attractive because it is simple and is a viable approach for ranking many FNs with respect to the same criteria. The concepts and methods developed by Tseng and Klein are attractive because they are robust, easy to understand, and fairly simple to implement. Other methods identified for prioritizing FNs utilize linear algebra and convolution of FNs (MAX/MIN Methods). These methods are viable but more complex to numerically implement on a computer.

B.2.1.4. <u>Developing a Fuzzy Logic System</u>

Fuzzy-logic-based system development is no different from the development process for any other microcontroller-based system (Kosko, 1994). Software development tools for fuzzy logic are not required but tend to simplify and enhance the job of developing the membership functions and rule base. Regardless of the development method, there must be a fuzzy inference engine to process the rule base. The inputs and desired outputs of the system or subsystem must be identified, the input and output membership functions must be defined, and knowledge about the problem space must be translated into a rule base. The rule base defines the behavior of the system.

Fuzzy logic offers a model-free approach to describing the behavior of a system. There is, however, nothing magic about fuzzy logic. Fuzzy logic is simply an approximation technique that quite often demonstrates superior performance to other methods when properly crafted. To craft an acceptable fuzzy logic system can become a significant challenge. Several factors can complicate the development of a fuzzy logic system. First, the number of fuzzy inputs into a fuzzy logic system, or subsystem, must be kept relatively small; otherwise the number of rules required to address all possible combinations of input values explodes geometrically. For example, just two input variables (each described by five membership functions) requires 5 x 5 (or 25) rules to fully define the system

behavior, 5 x 5 x 5 (or 125) rules for three input variables, 625 rules for four input variables, and so on. This geometric explosion of rules in fuzzy logic is a real problem and is addressed in a variety of ways. One of the most common solutions is to break the problem into subproblems (each containing only two to three input variables) and then aggregate the results in a hierarchical fashion. This method is not always easy to implement due to issues of exclusiveness of variables across rule clusters.

Other problems encountered in developing fuzzy logic systems include defining and tuning rules to achieve the desired behavior. Tuning rules is done by changing the weighted importance of individual rules, adding hedges, or even changing the rules themselves. A hedge operation is a method available to maintain close ties to natural language and allow for the generation of fuzzy statements through mathematical calculation (Brule, 1985). With any or all of these approaches, the task of defining and tuning a fuzzy system can be problematic and methods have been employed to assist developers in tuning their systems. One of the most elegant methods of defining and tuning fuzzy rules is through the use of neural networks. Often, one will find what is termed a neuro-fuzzy system in which a neural network is used to define and tune the rules of the system based on large data sets comprised of input/output values. This is an iterative process that continues until an optimal combination of rule definition and weighting (energy minimum) is obtained. Once this optimal state is determined, the neural network is disconnected and you simply have a fuzzy logic system.

B.2.1.5. Fuzzy Logic Development Tools

Fuzzy logic has matured enough in the United States that we are beginning to see the emergence of fuzzy logic and neuro-fuzzy logic development tools. These tools, which vary greatly in capability, performance, and price, were evaluated as part of the Phase I effort. A total of eight development tools were evaluated in Phase I. The primary criteria for evaluation were: (1) ability to generate code for a run-time portable fuzzy system (or subsystem); (2) whether the tools supported neuro-fuzzy system development; (3) cost; and (4) other factors, including stability of the company that owns the development tool, user friendliness of the development environment, internal testing facilities for newly developed systems, and quality and quantity of documentation and on-line support available for the tool.

FuzzyTech. The fuzzy system development platform that best satisfied these criteria was FuzzyTech. FuzzyTech is owned by a company named Inform Software Corporation. The Precompiler Edition generates portable C code, including the fuzzy inference engine, and supports Windows application development. In addition, there are no run-time license fees for distribution of products developed with FuzzyTech. FuzzyTech supports fuzzy rule definition and tuning with neural-nets, however, there is an add-on cost for the neural-net module. FuzzyTech appears to be one of the front runners in development platforms, particularly when commercialization is a primary goal. FuzzyTech is a mature product and has been extensively tested and applied to a variety of applications, including decision-support applications. OpTech recommends *FuzzyTech* as a development platform to be used in further design and development efforts of the TRAM System.

B.2.2. Case-Based Reasoning System

There are several analysis aspects of TRAM. These are the hazard identification function, which semiautomatically retrieves health and safety data for a material; the model and fuzzy- logic-based exposure assessment function, which is an essential simulation and estimation function; the construction and depiction of work environments, which is both a graphics and simulation function; and the risk management function, which is a complex and unique function for which no single approach will likely succeed. Risk management includes identifying potential alternatives for minimizing the risk posed to a worker by a hazardous chemical. This is an open-ended problem. There is no one solution, although

there is likely a set of best solutions for protecting the health and safety of a worker in a particular scenario. This set becomes more exclusive when cost considerations over the life cycle of the process are factored in as a decision parameter. Risk management cost factors should be addressed by TRAM. TRAM should also identify opportunities and provide suggestions for P^2 opportunities. In addition, TRAM should be capable of letting the user know that she/he is repeating a dangerous mistake made in the past (e.g., placing a pipe, which gets hotter with time as the product flows through it, next to a heat sensor for the entire building's fire suppression sprinkler system). In addition, OpTech believes a combination of methods would allow TRAM to perform all these functions better than it has ever been done before in an analysis and decision support environment. One of the key techniques to be used is case-based reasoning.

Cased-based reasoning is the use of old experiences to understand and solve new problems. Case-based reasoning can involve adapting old solutions to meet new demands; using old cases to explain new situations; using old cases to critique new solutions; or reasoning from precedents to interpret new situations (much like lawyers do) or create an equitable solution to a new problem (much like labor mediators do) (Kolodner, 1992).

In general, the second time at solving some problem or doing some task is easier than the first time, because we remember and repeat the previous solution. We are more competent the second time because we remember our mistakes and go out of our way to avoid them.

The quality of a case-based reasoner's solutions depends on four things: past experiences, ability to understand new situations in terms of those old experiences, adeptness at adaptation, and adeptness at evaluation.

The less experienced reasoner will always have fewer experiences to work with than the more experienced one, but the answers given by a less experienced reasoner won't necessarily be worse than those given by the experienced one if he/she is creative in understanding and adaptation. Programs written to automatically do case-based reasoning will need to be seeded with a representative store of experiences. Those experiences (cases) should cover the goals and subgoals that arise in reasoning and should include both successful and failed attempts at achieving those goals. Successful attempts will be used to propose solutions to new problems. Failed attempts will be used to warn of the potential for failure.

Understanding a new problem in terms of old experiences has two parts: recalling old experiences and interpreting the new situation in terms of the recalled experiences. The first is called the **indexing problem**. In broad terms, it means finding in memory the experience closest to a new situation. In narrower terms, it is the problem of assigning indexes to experiences stored in memory so they can be recalled for appropriate circumstances. Recalling cases appropriately is at the core of case-based reasoning.

Interpretation is the process of comparing the new situation to recalled experiences. When problem situations are interpreted, they are compared and contrasted to old problem situations. The result is an interpretation of the new situation. When new solutions to problems are compared to old solutions, the reasoner gains an understanding of the pros and cons of doing something a particular way. Generally, interpretation processes are used when problems are not well understood and there is a need to criticize a solution. When a problem is well understood, there is little need for interpretive processes.

Adaptation is the process of fixing up an old solution to meet the demands of the new situation. Various methods can be used to insert something new into an old solution, to delete something, or to make a substitution. Applying adaptation strategies straightforwardly results in competent but often unexciting answers. Creative answers result from applying adaptation strategies in novel ways.

One hallmark of a case-based reasoner is an ability to learn from its experiences, as a doctor might do when he/she caches a hard-to-solve problem so that it can be solved easily another time. To learn from experience, a reasoner requires feedback so that it can interpret what was right and wrong with its solutions. Without feedback, the reasoner might get faster at solving problems but would repeat mistakes and never increase its capabilities. Thus, **evaluation** and consequent **repair** are important contributors to the expertise of a case-based reasoner. Evaluation can be done in the context of the outcomes of other similar cases, can be based on feedback, or can be based on simulation.

Case-based reasoning provides many advantages for a reasoner in that it:

(1) allows the reasoner to propose solutions to problems quickly, avoiding the time necessary to derive those answers from scratch;

(2) allows a reasoner to propose solutions in domains that he/she/it doesn't understand completely;

(3) gives a reasoner a means of evaluating solutions when no algorithmic method is available for evaluation;

(4) is particularly useful for interpreting open-ended and ill-defined concepts;

(5) is particularly useful in warning of the potential for problems that have occurred in the past, thereby alerting a reasoner to take actions to avoid repeating past mistakes; and

(6) helps a reasoner to focus its reasoning on important parts of a problem by pointing out key problem elements.

NIOSH generates what is termed NIOSH alerts. These are good examples of a type of information that could be seeded in the risk management case-based reasoner. An example is NIOSH PUB. NO. 89-109, Preventing Death from Excessive Exposure to Chlorofluorocarbon 113 (CFC-113). NIOSH alerts, such as 89-109, are developed in response to the occurrence of one or more workplace incidents that have resulted in a health and safety problem, or even tragedy. The alerts describe methods for avoiding these past mistakes. These are perfect examples of the type of information with which to seed a case-based risk management knowledge base. Based on the advantages described above, and the fact that so much of risk management is knowing what has and has not worked in the past, OpTech looks at case-based reasoning as a viable contributor to a risk management function and possibly other functions.

B.3. Hazard Identification Function

B.3.1. Overview of Human Health Effects

Human health effects include many responses in humans caused by chemical exposure. Epidemiological data may be used to characterize health effects, but laboratory mammalian toxicity data are most often included in chemical ranking and scoring systems. The numbers and types of endpoints used to assess potential health effects vary significantly.

Criteria for evaluating health effects often include toxicity resulting from varying durations of exposure. Those effects resulting from acute, subchronic, and chronic exposure are commonly included in chemical ranking and scoring systems. A brief description of each of these types of effects is listed below.

Acute Effects. Acute toxicity tests usually involve a single dose and a 14-day observation period. These tests are most commonly conducted on a mouse or rat, but other species (such as a dog or rabbit) may be used. Acute effects are often characterized by lethality, commonly reported as the mammalian median lethal dose or concentration (LD_{50} or LC_{50}). This is the dose or concentration required to elicit lethality in 50 percent of the animals tested. Non-lethal acute effects are sometimes included as well. Skin or eye irritation and sensitization are examples of such effects. Routes of administration commonly preferred include oral, dermal, and inhalation exposure. Some systems use data from other routes of exposure in the absence of preferred data.

Subchronic Effects. The most common test duration for these tests is 90 days, but the exposure time may vary. The main goal of these studies is to determine the no-observed-effect-level (NOEL) and to identify the specific organs affected after repeated doses of the test substance. These tests are usually conducted on a rat by an oral route of administration, but other species and routes may be used (University of Tennessee, Center for Clean Products and Clean Technologies [UT, CCPCT, n.d.]).

Chronic Effects. Chronic effects tests are long-term (longer than 3 months) studies designed to assess the cumulative toxicity of chemicals (UT, CCPCT, n.d.). Chronic test data are often utilized in chemical scoring systems. Chronic health effects may be evaluated on the basis of a wide variety of toxicological endpoints. Carcinogenicity, mutagenicity, reproductive toxicity, teratogenicity, and other chronic toxic effects are often included in chemical scoring systems. General chronic effects may be characterized by reportable quantities (RQs), RfDs, threshold planning quantities (TPQs), the minimum effective dose (MED), or other measures. A brief description of the chronic effects often assessed in chemical ranking and scoring is provided below.

Carcinogenicity. Chemical carcinogens are substances which cause cancer in humans or other animals. Carcinogenicity is often evaluated on the basis of weight-of-evidence classifications developed by the EPA and/or strength-of-evidence classifications by the International Agency for Research on Cancer (IARC). Weight-of-evidence classification considers all long-term animal and relevant human studies as well as metabolism, pharmacokinetics and mechanistic information, structure-activity relationships (SARs), and other studies involving biochemical or physiological function. Strength-of-evidence classification may refer to the magnitude of conviction about the results of an experiment. For example, the National Toxicology Program (NTP) classifies each carcinogenic bioassay according to the amount and type of data from an experiment (Scala, 1993). The strength-of-evidence scheme developed by IARC excludes mechanistic information relating to the relevance to humans of bioassay data which show evidence of carcinogenesis in animals. This scheme is considered to be based on strength-of-evidence rather than weight-of-evidence (Ashby et al., 1990).

Sometimes one or both of the EPA and IARC classifications are combined with a measure of potency, usually the slope factor (q_1^*) or the ED_{10} in chemical ranking and scoring systems. Potency refers to the relationship between the dose and the response. The slope factor is an upper bound estimate of the probability of a response per unit intake of a chemical over a lifetime. It is used to estimate the probability of an individual developing cancer resulting from a lifetime exposure to a carcinogen (EPA, 1989b). This is the potency factor normally used in EPA risk assessments. The ED_{10} is the estimated dose associated with a lifetime cancer risk increase of 10 percent.

Mutagenicity Effects. Mutagenesis occurs when chemicals cause changes in the genetic material which can be transmitted during cell division (Klaassen and Eaton, 1993). Several procedures, both *in vitro* and *in vivo*, have been developed to test chemicals for possible mutagenicity. Tests for mutagenicity are often used to screen for potential carcinogenesis because the initiation of chemical carcinogenesis is believed to be a mutagenic occurrence (Klaassen and Eaton, 1993). Like carcinogenicity, mutagenicity is often evaluated according to weight-of-evidence classification which is sometimes combined with a measure of potency and/or severity. Mutagenic effects may also be of interest in terms of genetic alterations in the next generation.

Reproductive Toxicity. This refers to the occurrence of adverse effects, resulting from exposure to chemical or physical agents, on the male or female reproductive system. These may include effects on fertility, gestation, or lactation, among others (Klaassen Eaton, 1993). These effects are usually scored according to some type of weight-of-evidence and/or potency and severity.

Teratogenicity. Teratogenicity occurs when exposure to some chemical or physical agent induces defects during the development of an organism from conception to birth (Klaassen and Eaton, 1993). Teratogenicity is sometimes considered separately from other reproductive effects. Likewise, these effects are often scored on the basis of weight-of-evidence and/or some measure of potency and/or severity.

Neurotoxicity. This includes adverse effects on the nervous system caused by chemical exposure which may be structural and/or functional and may include behavioral changes and learning disabilities.

Acute, subchronic and chronic effects, carcinogenicity, mutagenicity, teratogenicity, and reproductive effects are health effects that would need to be addressed by the TRAM. In addition to health effects, TRAM should address safety issues associated with chemicals (e.g., flash point, explosive limits, conductivity, pH, etc.). An important aspect of the Phase I effort was to identify potential sources of the type of chemical information that would support the above chemical health and safety concerns. The following section summarizes these efforts.

B.3.2. Material Health and Safety Data

TRAM would require the presence of substance-specific data in order to carry out a workplace chemical risk assessment. The types of data that will be required include health effects data as well a physiochemical properties. One format considered, because of the wide range of data it contains and its wide spread application within the U.S., is the MSDS.

An MSDS must be prepared by the manufacturer of a chemical or material to be used under industrial occupational conditions. Types of data on a MSDS include hazardous ingredients, physical data, fire and explosion hazard data, health hazard data, reactivity data, special protection data, regulatory data and other special information of concern. The broad spectrum of data types included on MSDSs, including many elements desirable for TRAM, is a primary reason OpTech researched their use as one of the data sources and formats to be used within the system. One important document relating to MSDSs is ANSI Z400.1-1993, *American National Standard for Hazardous Industrial Chemicals - Material Safety Data Sheets- Preparation.*

This standard is developed to help MSDS preparers develop consistent, understandable MSDSs that provide useful information to a variety of audiences. The standard brings together many best practices from different companies and working groups in order to develop a consistent standardized format for future MSDSs. Therefore, it is unlikely that any one company currently follows all practices and procedures discussed in the standard. The American National Standards Institute (ANSI) acknowledges

that this standard is only the beginning of a long process. Chemical manufacturers will evaluate their own practices, decide on the best approach for their materials, and make revisions to their current MSDSs. In addition, the new ANSI standard identifies several new types of information to be included on MSDSs that were previously not part of the format. OpTech reviewed this standard, identifying data fields of possible applicability in TRAM. The use of MSDSs in an integrated electronic format (i.e., storage and full text search capabilities) in TRAM could be technically more plausible due to the standardization prescribed by ANSI Z400.1.

MSDS Data Manager. A related but separate issue is a method for making the MSDS data available to the TRAM user. Of several possible approaches, one would be to integrate a MSDS database into TRAM. There are several desirable aspects to this approach. The data would be resident on the machine, making it an easily accessible part of the system. This would prevent the user from having to physically locate, obtain, and enter the needed data from an MSDS into TRAM. In addition, an integrated database could relieve users of much of the responsibility in identifying information requested/needed by hazard identification functions within TRAM. This capability could be added through the development of an intelligent MSDS manager for use in TRAM. An MSDS manager such as this could take advantage of full-text search capabilities, content searching, pattern or character string recognition, and user knowledge elicitation techniques to simplify and expedite the acquisition of some of the data required in the risk assessment process.

The need for MSDS-type data is driven by variables in the risk assessment scenario. For instance, when the user specifies a substance to be used within a workplace scenario, the TRAM could automatically locate and obtain fundamental data associated with a chemical (e.g., health hazard data) and the values assigned to assessment variables. The MSDS manager would then identify scenario-dependent data in the MSDS database. If the scenario dictated that the worker enter a room containing a hazardous vapor for a short period of time, it is necessary to determine if an OSHA STEL and ceiling exist and, if they do, to retrieve their values. In a general sense, the MSDS data manager can be seen as a value finder, utilizing several resources, databases, and the user to supply the risk assessment routines with essential data. The MSDS manager would be a fairly sophisticated component of TRAM that functions primarily to reduce the complexity of, and the time spent on, developing and assessing a workplace environment.

MSDS Information Source. One attractive source of MSDS information identified during Phase I was the Hazardous Substances Data Bank (HSDB) produced by the National Library of Medicine (NLM). It is a factual database focusing on the toxicology of 4500 potentially hazardous chemicals. The HSDB is fully referenced and peer-reviewed by a Scientific Review Panel, and includes information on:

--Substance identification
--Pharmacology
--Manufacturing/use information
--Environmental fate/exposure potential
--Safety and handling
--Exposure standards and regulations
--Toxicity/biomedical effects
--Monitoring and analysis methods
--Chemical and physical properties
--References

The HSDB contains the same types of information found on an MSDS. In fact, the HSDB is a generic MSDS in that it does not contain manufacturer-specific information. However, all the information found on the MSDS is included in an HSDB record, including major manufacturers. The HSDB data is available on magnetic tape from the NLM under its data leasing program. The cost of leasing the data on tape from NLM is small and the data can be reused with very few restrictions. The data is formatted on the leased tapes in a way that facilitates reuse or incorporation into another system. At this point, OpTech would recommend the HSDB tapes for further design and development work due to the high quality and low downstream cost of the data.

B.3.3. Human Health Exposure Criteria Estimation

There will be cases in the hazard identification/dose-response function where human health data will not be available on the MSDS and, alternatively, the equivalent to a formal PEL or TLV must be estimated. This is especially the case for new materials that have not been subjected to subchronic or chronic toxicological testing. Our approach to handling this situation is to utilize toxicological screening data available on the MSDS, along with SARs, to estimate allowable chronic exposure in terms of the R_fD. This, in turn, forms a basis for estimating an allowable exposure dose such as the TWA PEL. The Hazard Identification Expert System (HIDES), developed in a previous Small Business Innovation Research (SBIR) project, will be utilized to obtain the R_fD estimate (Harrah, et.al., 1993). HIDES will be a subsystem within TRAM. In addition to the R_fD estimate for noncarcinogens and/or risk estimations (e.g., slope factors) for carcinogens, HIDES will generate confidence values associated with each health risk estimate. The system accepts a wide variety of inputs, including physical and chemical properties and data from toxicological studies. HIDES can also make use of many SARs in its estimates. HIDES was developed as a hybrid expert system and is capable of making estimates within data rich and data poor environments. It utilizes expert heuristics, object-oriented programming, and fuzzy logic to capture and utilize imprecise information typical of data-poor environments likely to be encountered by TRAM.

B.4. Exposure Assessment Function

B.4.1. Background on Exposure Assessment

To best understand the exposure assessment factors to be considered in the development of TRAM, a short review of the process is appropriate. Exposure assessment (Hawkins et al., 1993) is the process of measuring or estimating the intensity, frequency, and duration of human contact with agents present in the environment or hypothetical contact that might arise from their release into the environment. It is done for the purpose of estimating potential health risk, in parallel with dose-response (potency) assessment, as part of risk assessment, and to permit the evaluation of association or causation in epidemiology. Exposure assessment in the workplace is often performed by industrial hygienists, scientists, and engineers. Many research and regulatory agencies of the U.S. Government are involved in some aspect of exposure assessment.

The methods used to assess exposure vary widely and depend on the purpose of the assessment, the environmental medium, the time relationship of the exposure to the assessment, and the scientific and technical background of the exposure assessor. A sophisticated, in-depth exposure assessment may be needed to ensure that no individual is overexposed to a dangerous substance, whereas only screening exposure assessment may be needed as an approximate estimate of exposure for priority setting. Current exposures in existing facilities can usually be measured directly, but assessments for retrospective epidemiology are often estimates derived from indirect data and surrogates. In some instances, the exposure levels of potential concern are so low that they are analytically nondetectable;

therefore, modeling exposures is the only option. Engineers often rely on models and empirical handbook data in the design of new processes and systems.

Modeling. In general, exposure modeling uses a mathematical construction to estimate exposure. Classical modeling techniques define a source term for the contaminant and allow for transport and fate in time and space to predict concentrations. Receptors (e.g., people) are then integrated into the predicted exposure fields and their time-averaged exposures estimated. This is consistent with the NAS paradigm presented in Section B.1.3. Predictive modeling using both deterministic and empirical techniques will be used in the development of TRAM.

Time-Activity Patterns. Time-activity patterns are important in the modeling process. Models typically estimate a medium concentration of a contaminant as a function of time in a defined space. To estimate exposure, it is necessary to model the person's time distribution in the concentration and integrate the time-weighted average chemical concentration at the physiology-medium interface. The default assumption is typically that the person is in that volume for the entire potential time of exposure (e.g., 480 minutes of a working day).

A level of detail can be superimposed on these models that could dramatically lower the level of uncertainty and, most likely, the level of exposure and risk. **Job exposure profiling** is the process that seeks to place and time the worker in the workroom environment and allows a more refined estimation of exposure. A similar approach uses questionnaires or **time-activity diaries** in which persons are asked to recall daily activities, usually focusing on a single day. Most time-activity data have not been validated, but the reliability and validity of those that have been tested are encouraging.

Integrated Exposure Assessment and Uncertainty Analysis. Simply stated, the purpose of exposure assessment is to facilitate risk management decisions. If one is not going to ultimately evaluate the acceptability of a particular risk, its evaluation may be an unnecessary exercise. Indeed, it is the fundamental responsibility of any exposure or risk assessor to render risk management decisions or to communicate scientific information to those who do. Given this charge, the assessor has the difficult task of weighing all the information in the available knowledge base versus the uncertainty in those data to arrive at (or facilitate) risk management decisions.

Figure 6 illustrates the two major components of uncertainty in exposure and risk assessment. Because risk is the product of potency (i.e., probability of a health effect at a given dose) and exposure, both are equal partners in the determination of risk. It also follows that the uncertainty in each element drives the uncertainty in the overall assessment of risk.

When the probability distributions of the variables or uncertainties of each of the parameters and models used to arrive at the potency and exposure assessments are known, the overall probability distributions of the risk assessment can be determined. Combining the statistical distributions of many model components to determine the joint probability of some dependent variable is usually performed with a computer using a mathematical technique such as Monte Carlo simulation. If the probability distributions of potency and exposure are known, they can be combined to yield the joint probability distribution of risk. This is a much more useful presentation of risk than a point estimate because it gives the risk manager a view of the most likely risk, an upper bound, and the difference between them. This presentation of complete distribution of potential health risk would allow the risk manager to make better informed decisions. Fuzzy techniques also exist for dealing with uncertainty (Rasiowa, 1992) and would be evaluated for use in future work as appropriate. The proper "mix" of fuzzy and classical methods would need to be determined at that time.

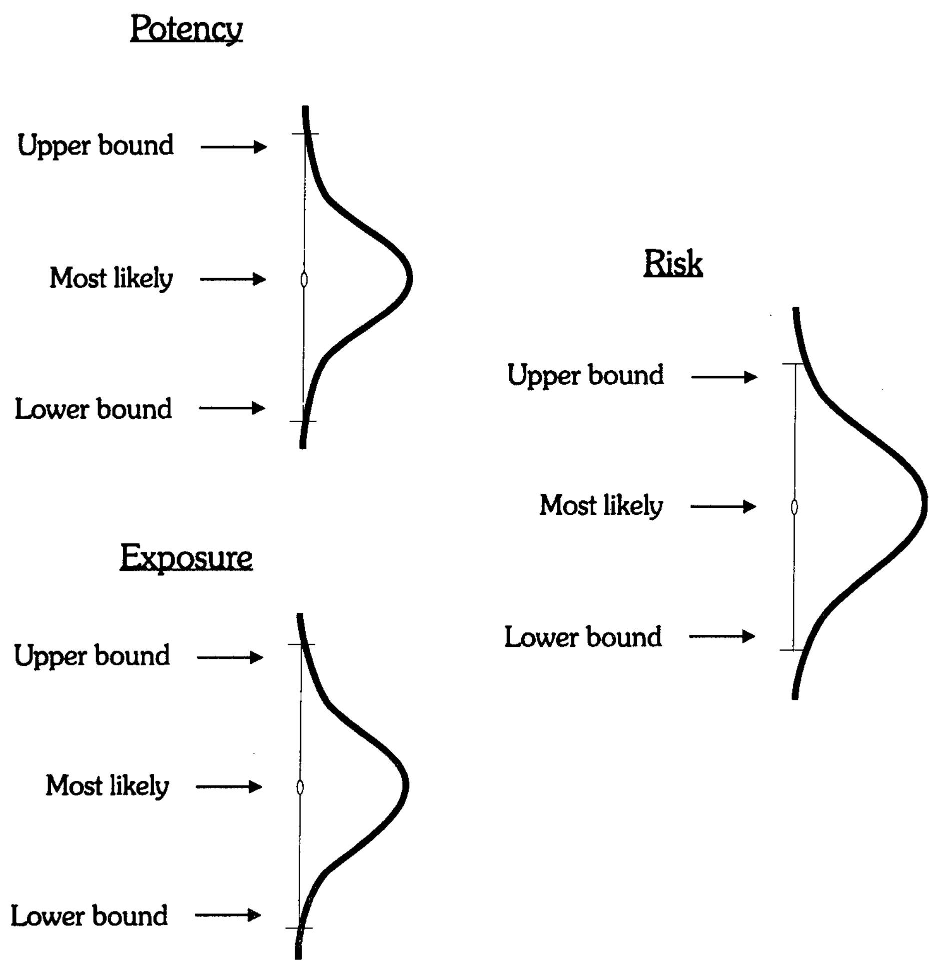


Figure 6. Uncertainty in Risk Arises from Uncertainty in Both Potency and Exposure (Risk = Potency x Exposure)

B.4.2. Process Simulation

Process flow models are needed to simulate task-based worker exposure. Computer-generated flow modeling also affords additional benefits. It can speed up the time to map plant processes, and can ultimately be linked directly with existing reporting software to automate report generation. Because reports must generally be updated on a periodic basis, a software-driven system becomes an excellent time saver.

Charting a manufacturing or maintenance process requires detailed knowledge of each unit operation and associated task analysis.* Charting this same process from a worker risk point of view requires the addition of detailed chemical data, raw material quantities, waste stream identification, and management. It must all be coupled with production volumes not only for each product line but more specifically for each production unit within the product line.

After the plant's chemical inventory is loaded, the software could "interview" the TRAM user about the flow charting process. What operation occurs first? What are its raw material inputs? What are its outputs? Where do these outputs go? What are the worker tasks and where (in the workspace and

process) do they take place. Each of these questions can be answered directly from knowledgeable plant personnel. For the less process-oriented user, the TRAM would guide the user to locate the required data.

In this manner, the process-modeling tool would guide the user in the creation of a precedence network for the complete manufacturing or maintenance process. For example, assume that welding, grinding, and painting represent particular production units in a process and that welding must be performed before grinding, followed by painting. This precedence information is used to generate a flow chart in much the same fashion as construction management software generates Program Evaluation and Review Technique (PERT) charts.

For more complex manufacturing processes composed of many more production units, a process flow diagram is an especially useful tool to identify, track, and tally what the manufacturer does at each step in the process. This is crucial to determining strategies necessary to optimize production flow and material cost, as well as to design engineering controls into the system for worker risk management.

Manufacturing plants vary widely in production methods. The TRAM will be designed to handle batch processing, continuous, and job-shop manufacturing because the software is process-oriented, not black-box oriented.

To support TRAM estimates of the exposure of workers to chemical agents, several modeling and analytical techniques would be brought together. They will include fuzzy estimation and fault tree techniques, air contaminant concentration models, dermal contact models, and simulation. With the exception of simulation, all these techniques must be implemented through innovative methods because no robust and efficient methods currently exist. The methods that do exist are either complex computationally, or very case-specific. Simulation techniques, too, have had to be defended on points (e.g., the accuracy of statistical distribution selection for event occurrences). Still, simulation techniques have been mastered to a large degree. TRAM requires simulation and queuing capability for characterizing the dynamics of the work process being evaluated. Types of TRAM simulation attributes include material queuing information, time-line task analysis of workers (including time spent in various areas of the work environment), mishap likelihood estimation, and process efficiency. In addition, TRAM would require discrete event simulation to drive the dynamics of the graphical workplace simulation. Because of these requirements and the advanced state of simulation tools, it is important to use proven simulation software as opposed to trying to "re-invent the wheel." As part of this study it was determined that Micro Saint is an acceptable simulation tool for the purposes of TRAM.

Micro Analysis and Design Incorporated, Boulder, Colorado, developed and owns Micro Saint. Micro Saint is a task network modeling tool that can be used to simulate discrete processes. Many applications have been in the realm of industrial engineering, such as assembly lines, job shops, factories, and so forth. For example, if you are considering the purchase of a new fabrication machine for an assembly line, you would probably want to conduct a simulation experiment first to determine the pay-back time. Thus, you construct a model of your assembly line, insert the new machine, and see if you really can make components faster. Maybe not-- perhaps you will find that the bottleneck is actually somewhere else in the system. With Micro Saint, you can watch parts flowing through the system, examine operators carrying out their duties, track queues building up at overworked stations, and so on.

The basic methodology includes constructing a model out of "tasks." Each task takes a certain time to complete, drawn from a selection of random distributions (normal, exponential, gamma, weibull, pareto, etc.). Tasks in a network diagram are connected by arrows that show the sequence between them. When one task completes, another begins. The branching logic can be based on probabilities, tactical expressions (written for goal seeking), or the task can take multiple paths. Task network modeling at the simplest level is similar to a flowchart. The diagram represents the sequence of operations. Micro Saint can put queues in front of each task, hold up the beginning of a task until certain conditions are met, decompose the entire operation into subnetworks, and perform many other sophistications. Many entities can travel through the same network at one time.

The core of Micro Saint is a simulation engine that processes events. Most of these events involve the execution of tasks from the task network in the proper sequence, but other external events can be added to represent external changes to the environment. The simulation engine keeps these events ordered by their clock value and changes the state of the system based on what occurs in each event. A parser allows the user to add algebraic and logical expressions for greater flexibility and modeling power. As entities flow through the network, the simulation engine highlights active tasks, changes variable values, and updates the event queue. Micro Analysis and Design would assist OpTech in the future, with the integration of Micro Saint's underlying simulation and queuing features into the TRAM system. They would also assist in validation studies specifically tied to the performance of Micro Saint.

Micro Analysis and Design has expertise in human factors, as applied to workplace design and human-computer interfaces. In their work with the U. S. government, they have developed a number of full-scale software products that analyze aspects of military and industrial operations (maintenance, workload, personnel requirements, performance degradation, etc.). They are the developers and marketers of Micro Saint, a commercially available simulation software package for MS-DOS, Microsoft Windows, UNIX, and the Macintosh operating systems. They have used Micro Saint in their own consulting work to build models of complex operations and analyze the areas of interest to their customers. In this project, their role was to provide simulation expertise to OpTech as it related to determining the feasibility of pursuing development of the TRAM System. Micro Saint is a tool that can run simulation experiments and collect data (e.g., time-based task analysis, task performance, and accident probabilities).

As part of a Phase I proof-of-concept demonstration, Micro Analysis and Design developed a demo based on Micro Saint that runs under Microsoft Windows 3.1. The demo uses Micro Saint and ToolBook, an authoring package from Asymetrix. This particular test case used in the demo is a bolt cleaning operation. The operation begins with the arrival of cages of 100 bolts coated with rust, oil, and other dirty residue. The bolts are cleaned in successive stages to prepare them for nickel plating. The cages of bolts are first soaked in a solution of Sodium Hydroxide and rinsed with water to remove heavy soil and grease. Next, they are pickled in Sulfuric Acid to remove rust and other particles. The third stage is a vibrating table that uses abrasive material (Aluminum Oxide with oil binder) to polish the bolts, followed by another rinse. The fourth and final stage is vapor degreasing with TrichloroEthane, which removes any remaining oil.

The operation employs three workers to oversee the bolt cleaning operation and assist in moving the cages from one station to the next. Around each station is a volume of air that may contain hazardous vapors. In this example, the objective is to track the time that the workers spend in these zones, possibly being exposed to potentially harmful chemicals. Via simulation we can experiment with several workplace designs and see which one results in the minimum amount of time the workers spend in these possibly highly contaminated volumes of air. Every so often the tanks are flushed and replaced

with clean solutions. Another objective is to track the total amount of waste liquid that is neutralized and sent to the drain or recycled.

This demonstration can be considered an early prototype for TRAM. It provides some early thoughts for the look and feel of TRAM, and explores some technical capabilities of its software components. Micro Analysis and Design created the prototype using screen sketches supplied by OpTech. The user might describe aspects of the system using dialog boxes, such as the one shown in Figure 7.

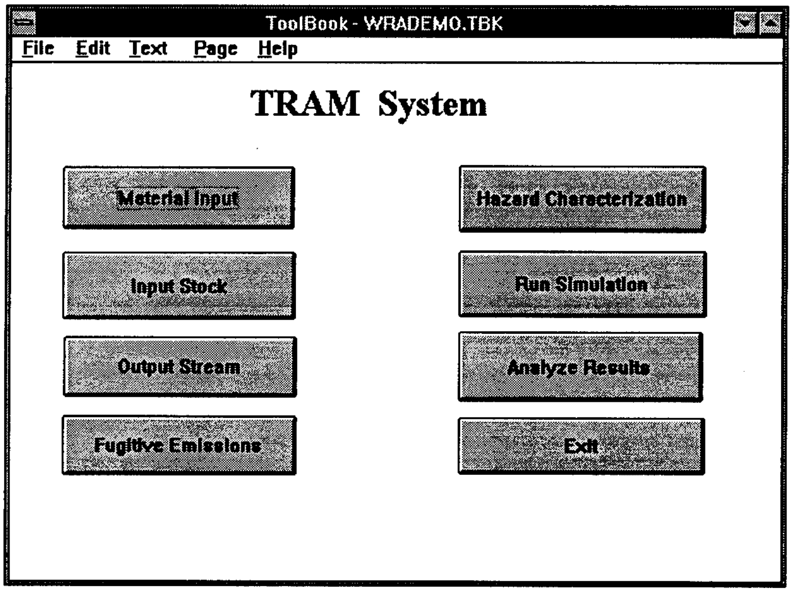


Figure 7. TRAM Demonstration Dialog Box

Pressing the button "Input Stock" displays the screen shown in Figure 8.

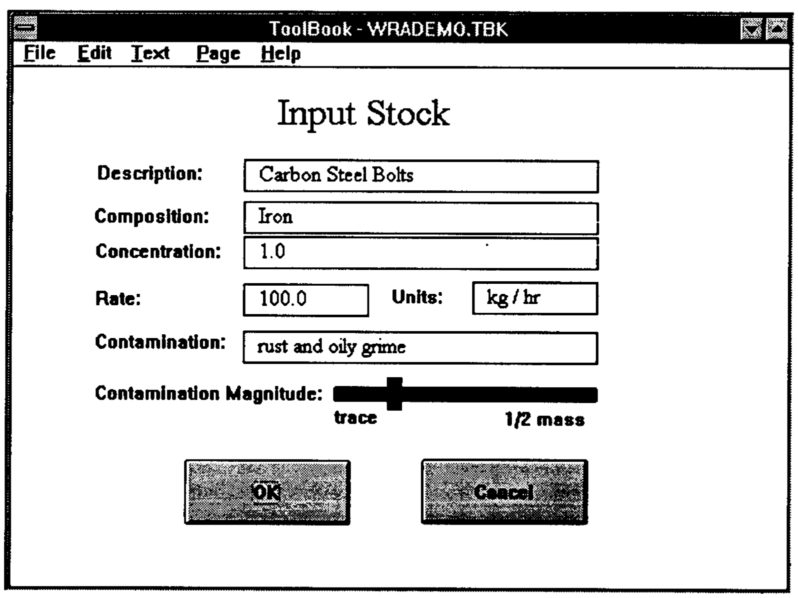


Figure 8. Input Stock Dialog Box

Micro Analysis and Design built a simple Micro Saint model of the bolt cleaning operation. OpTech supplied the process flow diagram, task times, and resource quantities. From this information, Micro Analysis and Design constructed the task network diagram shown in Figure 9.

Network 0 BOLT256

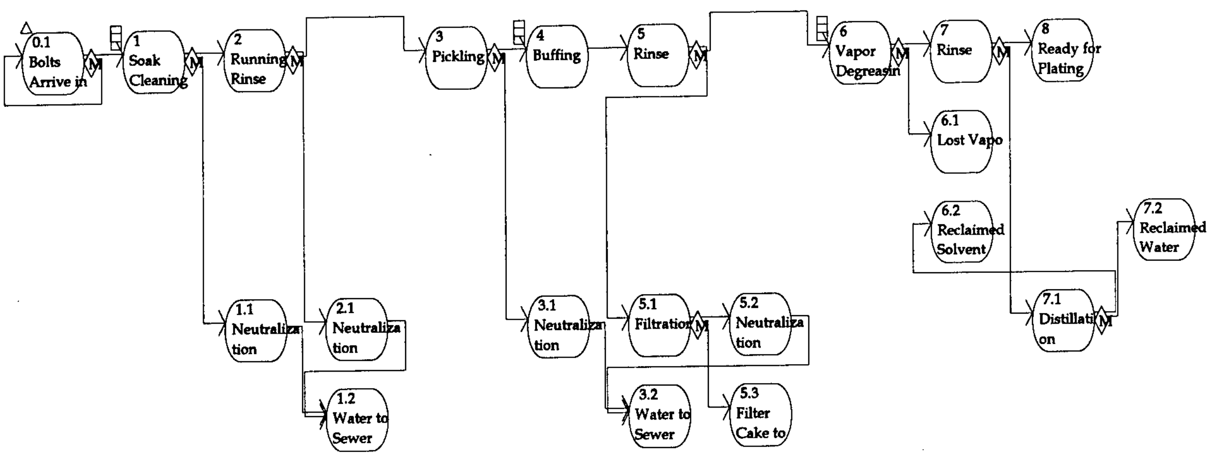


Figure 9. Task Network Diagram of Bolt-Cleaning Operation

This diagram shows the process flow of the entities in the simulation. The arrows between the tasks indicate the sequence between steps. This diagram can be animated as the model runs; however, OpTech and Micro Analysis and Design thought TRAM users might like to see a more realistic picture of the operation.

Micro Saint has a feature called ActionView that allows the user to show an animated view of icons moving over a graphical background. OpTech constructed a sketch of the workplace, showing the placement of cleaning stations and rinsing showers. Micro Analysis and Design drew a color picture of this workplace using Micrografx Designer, then pasted this picture into ActionView. Figure 10 shows the ActionView background as the model is running. Note the icons of bolts, human operators, and droplets of waste water.

The circles around Soak Cleaning, Pickling, and Vapor Degreaser represent zones of potentially high exposure. It is important to estimate the time operators spend within these zones. As Micro Saint executes the model, the user can observe the operators moving in and out of particular exposure ranges.

After the model completes, Micro Saint automatically quits and control returns to TRAM, where the risk assessment and management process continues. The data collected from the simulation can be either single-number measures (total waste water), or a series of numbers (exposure levels over time). The data can be presented in a tabular or graphical format, depending on what is most useful to the user.

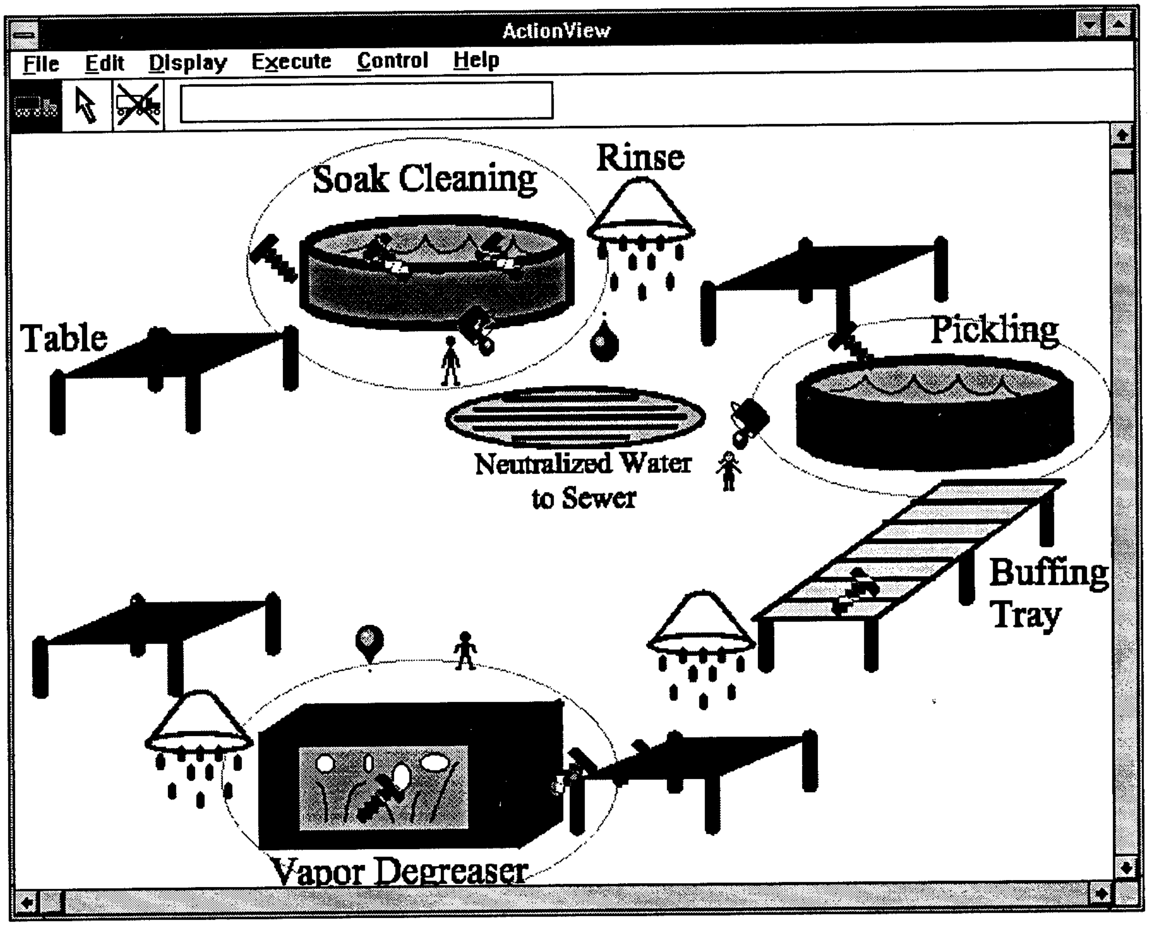


Figure 10. Action View Depiction of Bolt-Cleaning Operation

B.4.3. <u>Workplace Simulation</u>

Figure 11 illustrates a simple process that is representative of those found in maintenance areas. It is a degreasing process that might be associated with a metal finishing operation. It is not a closed, continuous system. Therefore, one or more human operators would be associated with the process to introduce the objects (to be cleaned) into the queue, transfer the objects between unit operations and, finally, remove the objects from the queue to a storage/use point. Within TRAM, this process could be simulated using Micro Saint. This is important for introducing time into the task-based risk estimation process, allowing the computation of TWAs (and peaks) for comparison to exposure standards or health effects criteria. Both the breathing zone and general workspace concentrations will be approximated. TRAM could contain a library of the fundamental work activities associated with the various operations and, given how the worker distributes his/her time over the workday/week (e.g., a single worker may work on a number of processes within the same general workspace within the same day), would generate the exposure and associated risk over time. TRAM should also provide useful information about the process, such as engineering controls that may be used for risk management. Occupational health information, related to such things as personal protective equipment and emergency response, should also be provided for decision-making as well as inclusion in documents (many mandatory), like hazard communications.

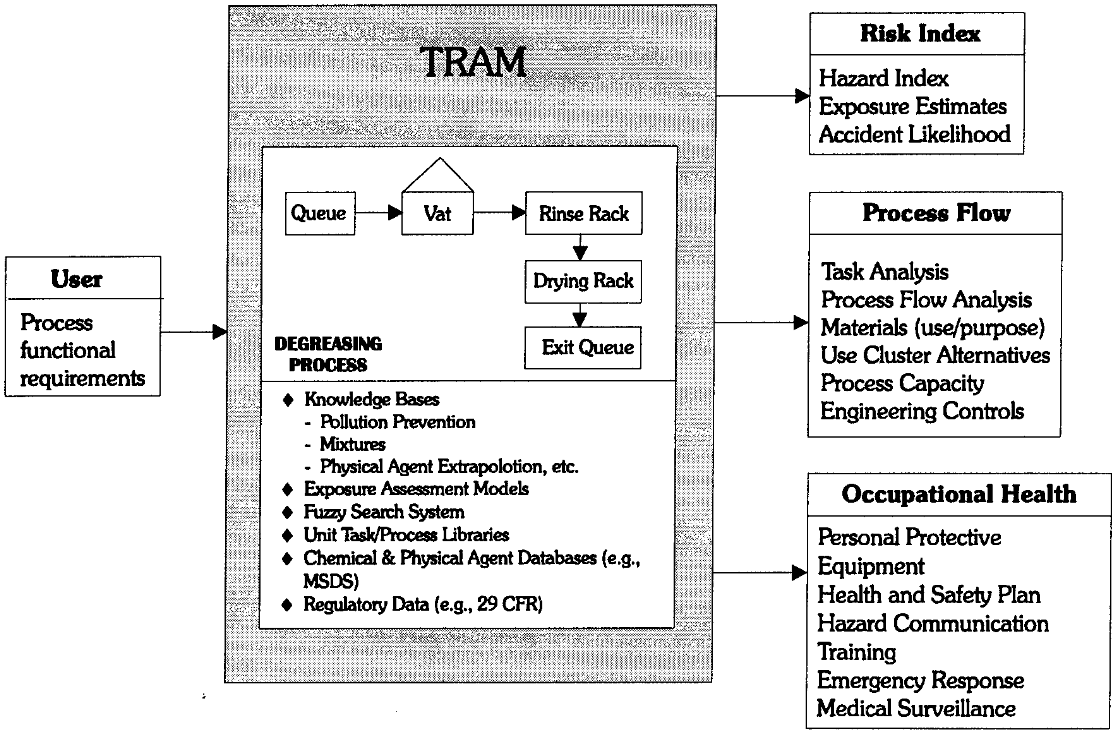


Figure 11. TRAM Working Concept Diagram

Contaminant Representation in the Workplace. The workplace can be thought of as a stirred tank (Haberline, 1993). Fluid (in this case air) flows in at one or more points and flows out at other points. Each of these airstreams has a concentration of a substance of interest associated with it. If the tank is perfectly mixed, the concentration of this substance flowing out will be equal to the concentration within the tank. Assuming the tank starts at some steady-state condition, the concentration of the incoming stream equals the concentration of the outgoing stream. The tank concentration will respond to a step change in concentration of the incoming stream (in this case, response is the deviation from steady-state conditions) as described by Equation 1,

$$X_{t2} = (C_{input} - C_{t1})\left(1 - e^{\frac{t_2 - t_1}{\tau}}\right) \qquad \textbf{(Eq-1)}$$

where:

- X_{t2} = the concentration response at a given time, t;
- t_1 = time 1;
- t_2 = time 2;
- C_{t1} = concentration in tank at time t_1;
- C_{input} = concentration of incoming stream at time t_2;

and

- τ = time constant.

For a stirred tank, the time constant can be described by Equation 2,

$$\tau = \frac{V}{Q} \tag{Eq-2}$$

where: V = the volume of the stirred tank, and
Q = the volumetric flow rate of the fluid.

The incoming concentration can also be restated in terms of a generation rate, as shown in Equation 3,

$$C_{input} = \frac{G}{Q} \tag{Eq-3}$$

where: G = the contaminant generation rate.

Substituting Equations 2 and 3 into Equation 1 and rearranging terms yields,

$$C_{t2} = \frac{G}{Q}[1 - e \, \frac{(t_2 - t_1)Q}{V}] + C_{t1} \, e \, \frac{(t_2 - t_1)Q}{V} \tag{Eq-4}$$

which is an equation describing dilution ventilation. This model is applicable to any defined volume within the workspace where perfect mixing occurs internal to the volume. This allows lumped parameter representation of the contaminant movement within a defined workspace, as illustrated below in the sequential box method. Mixing factors are often used in practice where perfect mixing cannot be assumed.

For workplace monitoring, however, determining the mixing factor will be more complicated than just estimating the mixing factor for a room. The volume of interest may be defined in a number of ways and may vary in size. If the exposure source is very close to the worker's breathing zone, this volume may be very small, say 0.09 m^3 (3 ft^3) in front of the worker. If the contaminant source is much farther from the worker, the volume may be considerably larger, up to the size of the room. The selection of this volume, as well as the activities of the worker, will affect the magnitude of the mixing factor. For design evaluation, using TRAM, the selected volumes within a larger work area may be selected so that perfect mixing is a reasonable assumption within each volume or box.

One very relevant paper by Haberlin 1993, describes a technique for predicting solvent concentrations resulting from coating the inside of bulk storage tanks with primer, paint and sealant. This confined workspace, though having some fundamental differences from the classical maintenance and/or manufacturing scenarios, provides useful information. Basically, a technique was presented to assess health risks associated with coating the inside surface of a bulk storage tank. The tank was 77 ft in diameter and 32 ft tall. It was ventilated, having one inlet vent and one outlet vent on top of the tank and one inlet vent near the bottom of the tank. The technique utilized a Sequential Box Model (SBM) to predict the time-varying solvent concentrations at arbitrary points inside the vessel during an ongoing coating process. Input parameters included volumetric flow rates of exhaust and makeup air, solvent

threshold limit values and evaporation rates, and a set of exchange coefficients that characterized air circulation inside the vessel. Also, the technique utilized a work task sequence.

The SBM methodology essentially allowed the tank volume to be divided into subvolumes (vertical slices), thus representing the tank as a lumped parameter system.

Task-Based Exposure Representation in the Workplace. Another particularly relevant paper (Nicas and Spear, 1993) developed a **task-based statistical model of a worker's exposure distribution**. The authors present a task-based model to describe a single worker's exposure to a single airborne chemical toxicant. The model accounts for variability in short-term (e.g., 15 minutes) TWA exposure values within a task, and for variability in arithmetic mean exposure levels between tasks. For a given workday, the eight-hour TWA value is equated with the sample mean of an appropriate number of short-term TWAs arising from stratified random sampling of short-term TWAs with proportional allocation by task. The model accounts for autocorrelation in the stochastic process that generates successive short-term TWA values. Due to the underlying random process, a given type of workday has an associated distribution, with regard to a set of task times. A worker's total distribution of eight-hour TWAs is a mixture of day-specific distributions weighted by the relative frequency of each type of workday; the variance of the total distribution increases with greater day-to-day variability in the array of task times.

Even for a single worker exposed to a single chemical toxicant, the assessment must account for an exposure variability within a workday and between workdays. Where the aim is to evaluate the risk of health damage, one must also focus on the appropriate toxicologically exposure parameter. For chemicals that exert primarily chronic toxicity and that have long biological half-lives (e.g., crystalline silica), the long-term average exposure level is the pertinent parameter. For chemicals that exert primarily acute toxicity and that have short biological half-lives (e.g., ammonia), the relative frequency of experiencing high short-term exposure levels is more toxicologically relevant. With respect to model structure and utility, the task-based model synthesized several ideas discussed in industrial hygiene literature.

Managing Workplace Exposure Information. Effective management of exposure information is important in existing operational scenarios and needs to be considered in the development of TRAM. A quality industrial hygiene program must include the collection and management of workplace exposure information. One approach to collecting and managing exposure information is through a **Job Exposure Profile (JEP)** system (Holzner et al., 1993). The JEP system provides a concise and detailed summary of exposure information for defined exposure groups that can be tracked over time. The value of the JEP system lies in its simplicity and versatility, both as a dynamic tool to be incorporated into a comprehensive occupational health program and as a historical document. The system serves as an effective method for identifying and focusing on significant health hazards for each job at a facility from industrial hygiene, medical, epidemiologic, and engineering perspectives.

A JEP is a compilation of estimated exposures to each chemical and physical agent encountered by employees in a single job classification at a specific work site during a defined period of time. A job classification designates a group of employees who are expected to have the same or similar exposure, (i.e., **homogeneous exposure group)**. The JEP includes a list of hazardous agents; the frequency, duration, and degree of employee exposure; the building/area locations and processes associated with exposure; a summary of employee exposure monitoring data; respirator and hearing protection used; the health effects associated with overexposure; and recommended medical surveillance for exposed employees. Exposure profiles are updated periodically to reflect changes in workplace exposures

resulting from process changes, introduction of new materials, or restructuring of job duties. JEPs are processed, stored, and reported, through a central corporate-wide computer database. Two useful concepts here are contact percent and degree of exposure.

Contact Percent is the percentage of the production year during which exposure to each hazardous agent occurs (i.e., the number of days per year a chemical is handled by an employee divided by the total number of days worked in the year). A contact percent of 100 implies that the material is handled every day worked. A contact percent of 40 means that on average, a material is handled two days out of five. The 40% contact could also be interpreted to mean that if an employee works 240 days/yr the chemical was handled on 96 of those days (240 days x 0.40 = 96 days).

Degree of Exposure is an estimate of the potential for exposure without consideration of the physical properties or health hazards of the material. The degree of exposure is estimated on the basis of the type of operation in which the hazardous agent is encountered and the availability and condition of control measures, excluding personal protective equipment. For example, the knowledge that a chemical is handled in a closed system is indicative of a lower exposure potential than the knowledge that the same chemical is manually poured into an open vessel. Like other exposure assessment strategies, professional judgement is required when developing JEPs; this is probably most important when determining the appropriate degree of exposure category. A numerical code for degree of exposure is entered by using the following criteria:

- Degree 1, or Minor Exposure. Operations conducted in closed processing systems or carried out in a laboratory hood.

- Degree 2, or Moderate Exposure. Operations conducted in open systems usually provided with local exhaust ventilation.

- Degree 3, or Major Exposure. Operations conducted without local exhaust ventilation or activities such as cleaning, maintenance, and repair.

Specific examples of each degree of exposure are presented in Table 2.

B.4.4. <u>Process Hazard Analysis</u>

When Congress enacted the Clean Air Act Amendment, it directed that, as part of the law, OSHA institute a standard covering *Process Safety Management (PSM)*. On May 26, 1992, that standard--*Process Hazard Management of Highly Hazardous Chemicals (29 CFR 1910.119)*--became law. The primary objective of OSHA's PSM standard is to prevent unwanted releases of hazardous chemicals, especially into locations that would expose employees and others to serious hazards (NUS Training Corporation, n.d.).

Interviews with potential users of TRAM indicated that the value of the system would be greatly enhanced if it would specifically address some of the requirements of the PSM standard, in particular, the process safety hazard requirement. Below is a summary of key points in the PSM.

The new OSHA standard has 16 paragraphs, the centerpiece of which is the *process hazard analysis (PHA)*. The PHA involves a *systematic review* of what could go wrong and what safeguards need to be in place to prevent a hazardous chemical release.

Table 2. Degree of Exposure Examples

Exposure Category	Task/Operation
Degree 1	bag filing, closed-system charging liquids/solids, closed-system forklift operation, laboratory operations in hood Polymerization, closed-system pumping, closed system spray drying
Degree 2	bag/drum filling, local exhaust ventilation bulk container filling, charging liquids/solids, local exhaust ventilation filtering, open painting--brush or roller sampling
Degree 3	bag/drum filling, unventilated filter changing cleaning--mix tank, reactor, spray dryer insulation repair/removal laboratory equipment cleanup

To be effective, the process hazard analysis evaluations must involve the entire process, which includes:

- process design,
- process technology,
- operational and maintenance activities and procedures,
- nonroutine activities and procedures,
- training programs, and
- all other elements that affect the process.

Employers must perform an initial hazard analysis, using at least one of six specified methodologies (What-If, Checklist, What-If/Checklist, HAZOP, FMEA, Fault Tree Analysis), or an appropriate, equivalent methodology. The selected methodology must be appropriate to the complexity of the process. PHAs must be completed on a five-year phase-in schedule and be performed in priority order, with the rationale for the priority documented by the employer. The rationale must include consideration of the process hazards, number of potentially affected employees, age of the process, and operating history.

To ensure that the safety of both plant and contractor employees is considered, the PSM standard clarifies the responsibilities of employers and contractors involved in work affecting covered processes. The standard also mandates employee participation in PSM programs, written operating procedures, employee training, pre-startup safety reviews, maintenance of the mechanical integrity of critical equipment, and written procedures for managing change.

A process is covered if it involves toxic or reactive highly hazardous chemicals contained on an OSHA specified list, at or above the specified threshold quantity. The threshold quantity is the amount of the chemical present at any given point in time, not aggregated over a period of time. A chemical distributed over several processes at less than the threshold quantity would not cause the process to fall under the standard, even though the chemical's cumulative quantity met or exceeded the specified threshold.

The new standard offers an integrated approach to chemical safety, putting the focus on a comprehensive management program. By integrating technologies, procedures, and management practices, companies can develop a health and safety strategy that effectively addresses their specific processes and will help prevent potential releases of toxic and/or flammable gases and liquids, explosives, and pyrotechnics. TRAM should support the PHA process.

With contributions from models and concepts, such as those described above, OpTech would be able to incorporate a flexible and fully operational exposure assessment capability into TRAM. In addition to process simulation, fuzzy logic would be used to model a mix of quantitative, qualitative, and linguistic operations in exposure assessment (e.g., implementing Table 2, Degree of Exposure Descriptors).

B.5. Risk Estimation Function

Risk-based ranking and scoring systems can be used to focus attention and resources on the largest potential hazards. Risk-based chemical ranking and scoring combines an assessment of both the toxic effects of chemicals (human and/or environmental) and the potential exposure to those chemicals to provide a relative evaluation of risk. Along with toxicity and exposure, ranking and scoring systems may include other environmental impacts (e.g., ozone depletion) and some measure of economic impact and/or societal value (UT, CCPCT, n.d.).

Chemical ranking and scoring systems are typically intended to be fairly simple and quick methods for determining the health and environmental hazards posed by the use and release of chemical substances. Although not intended to provide a quantitative assessment of risk, the majority of the systems reviewed do employ the basic principles of risk assessment for chemical ranking and scoring.

Chemical risk is a product of both toxicity and exposure. Most chemical ranking and scoring systems include measures of both toxicity and exposure and, in this way, are similar to quantitative risk assessment methods. The major difference is the extent to which the exposure assessment is performed.

Exposure assessment, in a quantitative risk assessment, involves an analysis of contaminant releases, identification of exposed populations, identification of all potential exposure pathways, an estimation of exposure point concentrations, and contaminant intakes. The exposure assessment results in an estimate of the magnitude, frequency, and duration of actual or potential human exposures through various pathways expressed as a total dose. None of the chemical ranking and scoring systems reviewed include a detailed site-specific quantitative risk assessment.

The final step in a baseline risk assessment is risk characterization. Here, chemical toxicity data are combined with potential exposure levels for the receptors of interest at a site to arrive at a quantitative estimate of the risk that receptors will suffer adverse effects. Such site-specific characterization is not generally performed in chemical ranking and scoring, but most of the systems reviewed do combine toxicity and exposure in some manner to score, select, or prioritize chemicals. Three relevant methods for the workplace scenario to be addressed by TRAM are the General Risk Index, the EPA Chemical Clusters Methodology, and Risk Assessment Code.

B.5.1. General Risk Index

A practical method (Sampaolo and Binetti, 1989), useful for priority selection among existing chemicals and for the assessment of the chemical hazard risks associated with different exposure pathways, will now be described in more detail to illustrate the approach.

The method is based on the attribution of scores to a list of physiochemical (PCP), toxicological (TP), and ecotoxicological (ETP) properties, considered mutually additive and capable of pointing out the intrinsic danger of the substance under examination. According to the specific risk aspects taken into consideration, it is possible to evaluate the intrinsic potentiality of producing physical effects, toxic effects (in general or specifically depending on the particular type of exposure), and environmental effects.

The attribution of scores is possible, both when the experimental data are available and when they are not available, by using simple alternative criteria based either on more elementary data generally available or on the structure/activity relationship. In such a way it is always possible to ascribe a score to each property.

Intrinsic properties also have to be considered in relation to several external exposure factors, capable of either increasing or decreasing proportionally the intrinsic danger. Such factors are different, whether we consider direct personal exposure or environmental exposure. Since this effort concerns workplace risk, only the direct personal exposure will be considered.

This model in its entirety is broader than the scope of TRAM. However, several elements of the original and enhanced models may prove useful in future work. The elements include considerations of direct personal exposure and toxicological and physiochemical properties. The General Risk Index (GRI) is one of the more significant formulas in the model. It integrates toxicological, physiochemical, direct human exposure, and ecological exposure data to determine an overall risk rating (Index). The GRI is expressed in a formal equation:

$$\mathbf{GRI} = \frac{\mathbf{(PCP + TP + ETP) \times (Q \times BC) \times (PDE + (ED \times P)) \times RP}}{\mathbf{6300}} \mathbf{\times 100}$$

where

PCP = sum of scores ascribed for physiochemical properties,
TP = sum of scores ascribed for toxicological properties,
Q = score for quantity on the market,
PDE = score for plurality of direct personal exposure,
BC = score for bioconcentration ,
RP = score for size of risk population,
ETP,ED & P are directly related to ecological concerns, and
6300 = sum of maximum ascribable scores for all parameters in the GRI.

This model can, however, be applied to workplace risk alone by simply removing the ecological exposure and appropriate physiochemical properties,

$$\mathbf{GRI\ workplace} = \frac{\mathbf{(PCP + TP) \times Q \times BC \times PDE \times RP}}{\mathbf{270}} \mathbf{\times 100}$$

where, ecological parameters ETP, ED and P have been removed, and 270 is now the maximum ascribable score in the denominator.

Lists of chemicals being considered for a particular application can all be ascribed a score (percentage) through some appropriate modification of the GRI such as shown above. They can then be ranked by Risk Indices, within use groups, for selection or further investigation. Inclusion of some fundamental concepts of the model may add value to the ability of TRAM to help designers prioritize substance/chemical options. However, there should be further investigation of two shortcomings in the GRI approach.

First, the numerical ranges used for scoring a particular parameter (e.g., 0 to 2 for molecular weight), often do not provide enough discrimination between the possible range of true molecular weights. For example, it may be more realistic to provide a wider range (e.g., 0 to 10) and/or a linguistic scale to use in scoring a parameter.

Second, the mathematical approach used in the model is simple. This in itself is attractive. However, it may be too simple to capture the complexity in synthesizing the elements and uncertainties of a risk assessment. There is uncertainty in both the assigning of values to individual parameters (e.g., molecular weight in TRAM) and in assumptions for aggregating parameters within a scoring group (e.g., toxicological properties). There are techniques for handling this type of uncertainty in a more accurate and robust manner (e.g., with fuzzy ranking, estimation, and priority setting).

B.5.2. <u>Chemical Use Clusters Scoring Methodology</u>

The Toxic Substances Control Act (TSCA) allows the EPA to regulate chemicals or chemical mixtures that present an unreasonable risk of injury to health or the environment. Currently, more than 70,000 chemicals are believed to be in commerce, and determining which of these chemicals are of the most concern is a formidable task. Historically, the problem has largely been approached by choosing chemicals to evaluate based on receipt of hazard data newly submitted by the manufacturer; at the request of EPA offices, government agencies, or interested parties; or by targeting specific sets of chemicals, such as those listed on the Toxic Releases Inventory (TRI) or chemicals which are persistent bioaccumulators. While this approach created a manageable set of chemicals to evaluate, it has not comprehensively addressed potential toxic issues. The use cluster scoring system described is one tool that may be used in the future to systematically identify and screen concerns related to a greater number of chemicals in commerce. The chemical use cluster concept has been developed and adopted by the EPA to improve both the risk assessment process and the results of chemical review.

The initial step in using the scoring system is to create chemical-use clusters (i.e., a set of competing chemicals and technologies for a given use). This streamlines the process of identifying candidate chemicals and their substitutes. By screening a set of chemicals that are substitutes for each other in a particular application for potential health and environmental risks and comparing them against each other to set priorities for action, risk reduction and pollution prevention may be achieved more quickly. The use clusters may also provide an initial indication of potentially safer substitutes for extremely toxic chemicals.

A set of 54 chemical-use clusters that can be used with the scoring methodology is the European Communities functional use categories, developed by the Commission of the European Communities Directorate-General Environment, Nuclear Safety and Civil Protection, 1991. Example functional-use categories include Adhesives, Solvents, Aerosol Propellants, and so forth. When applying the scoring methodology, it may be that a production or maintenance process under study will use multiple clusters. Table 3 illustrates a hypothetical degreasing process that requires three use clusters.

Table 3. Hypotyhetical Degreasing Process

Solvents
Aerosol Propellants
Corrosion Inhibitors

Once member chemicals for each cluster are identified, data is collected on:

- potential human and ecological exposure,
- potential human and ecological hazard,
- pollution prevention potential, and
- past EPA regulatory interest.

These elements are combined to create a score for each of the chemicals. The individual chemical scores are then combined to produce an overall cluster score that can be used to rank the clusters into high, medium, and low concern categories. In relation to TRAM, there is only the need to address workspace-related attributes in the scoring system, including human hazard potential, human exposure potential, and inherent toxicological risk associated with each chemical.

Human Exposure Potential. Human exposure potential includes the following considerations:

- use volume,
- total releases to the environment,
- consumer use,
- number of potentially exposed workers,
- number of use sites,
- bioaccumulation (Log P(octanol/water partition coefficient), and
- environmental persistence.

When human exposure potential is combined with hazard potential, a measure of risk or the probability of a toxic effect occurring is the result. When scoring hazard potential, the data collected for use are structured in a hierarchical fashion based on data quality. If the data from the highest quality category are available, then the highest score from that group is taken as the chemical hazard score. If high-quality data are not available, medium-quality data are used. Likewise, if medium-quality data are not used, low-quality data are used. Each chemical is scored separately for carcinogenic and noncarcinogenic effects.

Noncarcinogen Ranking Data.

<u>HIGH QUALITY</u>
Reference Dose (RfD)
Reference Concentration (RfC)
Reportable Quantity (RQ)
Threshold Planning Quantity (TPQ)
Human Health Water Quality Criteria (HHWQC)

MEDIUM QUALITY
Chronic No Observable Adverse Effect Level (NOAEL)
Chronic Lowest Observable Adverse Effect Level (LOAEL)
Subchronic NOAEL
Subchronic LOAEL

LOW QUALITY
Human Health Structure Activity Team Rank
Chemical Category Human Toxicity Estimate
TSCA Section 8(e) Submission

Carcinogenic ranking is structured in a format similar to that of nocarcinogenic data and includes as primary data cancer potency, RQ potency factors, and organizational classification as to carcinogenicity. All the ranking data including human exposure potential are assigned ranges of values for ranking. For example, under high-quality **noncarcinogenic** ranking data, the RfD is assigned the following ranges of ranking values:

<0.001 mg/kg/day is High
0.001 - 0.1 mg/kg/day is Medium
> 0.1 mg/kg/day is Low

With human exposure potential, bioaccumulation (Log P(octanol/water partition coefficient)) is assigned the following ranges:

> = 4.3 is High
< 4.3 - 3.5 is Medium
< 3.5 is Low

In addition to human hazard and exposure potential, a pollution prevention potential score is assigned. Pollution prevention is one of the highest priorities of the EPA, as declared in the Pollution Prevention Act of 1990. Reduction of waste at the source is the highest objective. The scoring system accounts for two considerations: (1) chemical release reduction potential and (2) risk reduction through safer substitutes.

To obtain the human risk reduction potential score, the human exposure potential score (1 for low, 2 for medium, and 3 for high) is multiplied with the hazard chemical score (1 for low, 2 for medium, and 3 for high). A high score indicates a greater potential for risk reduction or pollution prevention. This is shown in Table 4.

A sample cluster for pharmaceutical solvents showing human health risk reduction potential scores is presented in Table 5.

Each cluster is then scored by subtracting the lowest chemical score for human health risk reduction potential from the highest chemical score within the given cluster. The resulting numeric score can range from zero to eight. These scores are then grouped into categories for a final cluster score of low, medium, or high, as shown in Table 6. A high cluster score indicates a greater potential for reducing risk through substitution of chemicals within the cluster.

Table 4. Human Health Risk Reduction Potential Score

Human Hazard X	Human Exposure	= Human Health Risk Reduction Potential Score
High	High	9
High	Medium	6
Medium	High	6
Medium	Medium	4
High	Low	3
Low	High	3
Medium	Low	2
Low	Medium	2
Low	Low	1

Table 5. Sample Cluster for Pharmaceutical Solvents

CAS Number	Chemical Name	Human Exposure Potential Score	Human Hazard Potential Score	Human Health Risk Potential Score
71-55-6	1,1,1 Trichloroethane	High	Medium	6
75-35-4	1,1-Dichloroethylene	Medium	High	6
67-64-1	Acetone	High	Medium	6
7664-41-7	Ammonia	High	Medium	6
71-43-2	Benzene	Medium	High	6
56-23-5	Carbon Tetrachloride	High	High	9
67-66-3	Chloroform	Medium	High	6
64-17-5	Ethyl Alcohol	High	Medium	6
67-63-0	Isopropyl Alcohol	High	Low	3
67-56-1	Methanol	High	Low	3
108-10-1	Methyl Isobutyl Ketone	High	Medium	6
75-09-2	Methylene Chloride	High	High	9
108-88-3	Toluene	High	Medium	6
1330-20-7	Xylene	High	Medium	6

Table 6. Cluster Scoring

Numeric Score (Highest Risk Reduction Potential Chemical Score - Lowest Risk Reduction Potential Chemical Score)	Final Risk Reduction Potential Cluster Score
6-8	High
3-5	Medium
0-2	Low

Using this method, the hypothetical example from the Table 3 might have a cluster score of 6 (9 highest score - 3 lowest score); therefore it would have a human health reduction potential score of High.

In the cluster methodology presented in the draft EPA report, ecological exposure and hazard potential scores are also determined. Then, a final overall pollution prevention cluster score is developed by comparing human health risk potential and/or ecological potential with a release reduction potential score. A release reduction potential score was not discussed but is obtained by taking the ratio of releases to use (for those chemicals reported through the Toxic Releases Inventory (TRI)). In addition, an EPA interest score is worked into the overall cluster scoring process.

With respect to TRAM, not all aspects of the use cluster scoring methodology are of practical use. Specifically, we have put boundaries on what would be analyzed by TRAM. This includes all workplace concerns but only addresses environmental concerns (e.g., EPA concerns) as they interface with the workplace. This includes pollution prevention concerns, since the EPA's primary interest is to reduce waste releases mainly by reduction at the source (i.e., the workplace). It also includes relevant portions of regulatory measures such as RCRA, the TRI, CAA, TSCA, and so on. Therefore, with respect to the use clusters scoring methodology, OpTech would use those parts that cross over into the workplace. Those aspects have been highlighted in this report. The use clusters scoring methodology should add value by providing initial direction and alternatives for the user of TRAM in developing alternative processes to ones that might pose unacceptable risks.

B.5.3. <u>Risk Assessment Code</u>

Another approach reviewed during Phase I was AFR 127-12, "Occupational Safety, Fire Prevention and Health Program," which addresses abatement and risk assessment. This Air Force Regulation (AFR) illustrates the use of predictive risk assessment for prioritization and ranking of abatement projects. Below is a brief summary of the prescribed procedures.

Each occupational hazard or deficiency occurring within Air Force facilities must be evaluated and assigned a Risk Assessment Code (RAC). RAC assignments are made by qualified individuals in the safety and bioenvironmental engineering offices. RAC assignments are based on the *Hazard Severity* and the *Probability of a Mishap*. There are procedures for determining each of these.

The *Hazard Severity* is an assessment of the expected consequence if a hazard results from a mishap. It is defined by the degree of injury, occupational illness, resource loss, or damage that could occur. The severity categories range from I to IV and can be abbreviated as (I) death or permanent total disability, (II) permanent partial disability, (III) lost workday, and (IV) first aid or minor medical treatment.

Mishap Probability is an assessment of the likelihood that a hazard will occur as the result of a mishap. Mishap probabilities are categorized as: (A) likely to occur immediately or within a short period of time, (B) probably will occur in time, (C) possible to occur in time, and (D) unlikely to occur.

Mishap Probability and Hazard Severity are then brought together on a table to determine an RAC. The resulting RAC descriptors are (1) imminent danger, (2) serious, (3) moderate, (4) minor, and (5) negligible. There are prescriptive action items that must occur depending on this final RAC ranking. The generic table showing the relationship between Hazard Severity, Mishap Probability and the RAC is shown in Table 7.

Table 7. Risk Assessment Code Matrix

	Mishap Probability				
Severity	**A**	**B**	**C**	**D**	**Risk Assessment Code**
I	1	1	2	3	
II	1	2	3	4	
III	2	3	4	5	
IV	3	4	5	5	

The prioritization of prescriptive actions is accomplished by assigning an Abatement Priority Number (APN). The APN is a two-part code consisting of the RAC and the Cost Effectiveness Index (CEI). The CEI is a measure of the cost effectiveness of a hazard abatement project and represents a ratio of the project cost and its potential effectiveness. To calculate a CEI, an estimate of the abatement project cost is required as well as an estimate of the number of personnel exposed on a daily basis. With the CEI for each abatement project determined, the projects can then be prioritized by APN. An example of a prioritized list is shown in Table 8.

Table 8. Abatement Priority Number Index

RAC	CEI	APN	PRIORITY
1	(3)	1(3)	1
1	(113)	1(113)	2
2	(4)	2(4)	3
2	(15)	2(15)	4
2	(96)	2(96)	5
3	(11)	3(11)	6
3	(180)	3(180)	7
3	(240)	3(240)	8
3	(350)	3(350)	9

Although the above scheme is used for prioritizing hazard abatement projects, the principle elements used in predictive risk assessment are embodied within the process. Hazard Identification and Dose-Response are addressed through *Hazard Severity*. Exposure estimates are made at a macro level (i.e., the number of personnel exposed on a daily basis) and essentially a risk characterization is determined through the development of the APN. In addition, costs are factored in as a consideration in setting

priorities. It is reasonable to expect that many predictive risk assessment strategies follow the same line of thought. The primary difference is that exposure data must be estimated as opposed to being measured. The RAC process is similar to the Process Hazard Analysis of the OSHA PSM standard and is considered an important function to be supported by the TRAM system.

B.6. Risk Management Function

Risk assessment functionally interfaces with risk management in deciding how to protect worker health. That is, risk assessment provides information on the health risk, and risk management is the action taken based on that information. Risk management is generally an iterative process of identifying the regulatory and nonregulatory alternatives for abating unacceptable risk, evaluating expected cost-effectiveness of these alternatives, and designing an implementation method to correspond to the least-costly method of achieving the desired reduction in risk. There are numerous factors that will influence the chosen risk management strategy. For example, some risk management decisions are not only technically complex, (e.g., multiple exposures, multiple pathways), but are also be influenced by multiple applicable regulations. In addition, they may also involve sociopolitical, ethical, judicial, and legal factors (e.g., worker's perception of risk, etc.). Typically, the preferred order of workplace risk management is engineering controls (e.g., local ventilation hoods), administrative controls (e.g., crew rotation), and, least preferred, personal protective equipment (e.g., gloves, full face mask, etc.) (National Safety Council, 1982). Cost-effective risk management, in most practical cases, involves a "mix" of the three categorical approaches. TRAM will suggest candidate risk management actions as indicated by the task-based risk analysis, past solutions to similar problems (case-based reasoning), and cost inferences.

C. FUTURE WORK

C.1. Technical Objectives

As indicated in Figure 12, TRAM research is interdisciplinary and involves the three major scientific areas of human factors, occupational health, and computer science. A supporting discipline is information science. Future design and development work on the TRAM system should be supported by all four disciplinary areas.

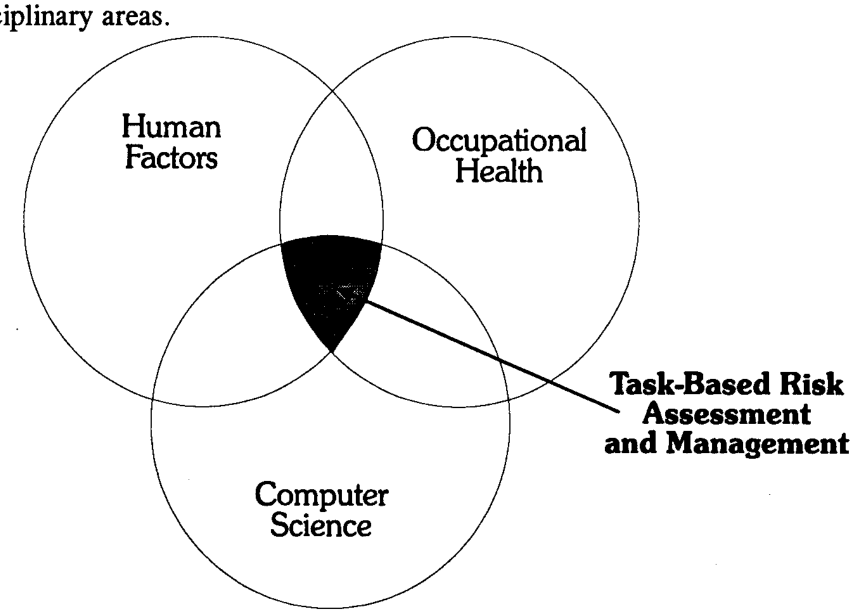


Figure 12. Interdisciplinary Nature of TRAM Research

As a result of the Phase I research findings, OpTech was able to develop eight “next-step” technical objectives for future work. These are listed below.

The overall objective should be to develop and demonstrate a fully functional and user- friendly microcomputer-based chemical risk assessment tool for application in work environments. The tool would be used to assist in designing and/or evaluating combinations of materials, processes, worker tasks, and work environment characteristics for the purpose of identifying "nearly optimal" risk management solutions based on generated risk indices. The specific lower-level technical objectives leading to this overall objective are as follow.

Develop and implement reasoning systems. Critical to the performance and ultimate success of TRAM is the appropriate application of fuzzy logic and case-based reasoning techniques. To ensure this is accomplished, current issues in each of the four critical disciplinary areas should continue to be rigorously addressed concurrently with design and development efforts. This includes tracking trends in the literature, taking advantage of software development aids and tools, and maintaining close ties with each of the essential scientific communities.

Develop hazard identification function. The hazard identification function will ease the burden on the user in collecting the necessary chemical, health, and safety data required for risk assessment. This should be accomplished through a substantial internal database of hazardous chemical data and unique data search and retrieval capabilities. Key criteria used in the Phase I evaluation of the data source were adequacy of the data ease of integration, and cost to the end user. To further ease the burden on the user, search features should be developed that will automatically retrieve needed chemical data based on the material specified and the use scenario. Manual data entry should be allowed for those chemicals not located in the database.

Develop exposure assessment function. This effort should develop TRAM models and reasoning techniques to allow system estimates of the nature, magnitude, and frequency of worker exposures to various hazardous materials. To ensure that accurate estimations are being generated, models and techniques need to be validated with monitoring data and/or epidemiological data sets collected from actual work environments. This will permit "tuning" of the TRAM system.

Develop risk estimation function. For the purposes of describing the risk associated with workplace hazards, and as a measure for comparing and evaluating different user-postulated work scenarios, a General Risk Index (GRI) should be developed and included as part of TRAM. The objective shouild be to provide a GRI that not only estimates the risk level but also identifies sources of the risk (e.g., worker being placed in close proximity to hazardous material for too long without a break).

Develop risk management function. This function should employ case-based reasoning, fuzzy logic, and rule bases to assist the user in identifying the best method for minimizing the risk identified in the workplace. TRAM should address changes in process design, worker task/job design, material substitution, and changes in the work environment (e.g., fresh air exchange rates).

Integrate system elements. TRAM functional elements will be integrated into a comprehensive and automatic, interactive system to provide the user with an almost seamless transition between the different steps and procedures in the risk assessment and management process. OpTech views this as a necessity in making the product appealing to end users. It should be accomplished by emphasizing rapid prototyping early in future efforts to ensure that a gestalt of TRAM is synthesized and adhered to

in design and development (i.e., ensure that through the process of planting trees [component functions], a forest [integrated system] is constructed).

Validate system. Validation studies of risk assessment and management functions should be performed on early TRAM products. Where possible, validation should be conducted using monitoring data and real risk assessment and management decisions from actual work environments to see how well TRAM performs compared to a bench mark operation. Where real data does not exist for validation, simulation techniques could be used to validate system functions.

C.2. <u>Systems Development Methodology</u>

It is essential that the user find TRAM both functionally and aesthetically appealing. The user interface is critical to system acceptance and approval; therefore, a comprehensive interface development plan was initiated in Phase I and should be continued in future design efforts. The process includes (1) early focus on users and their tasks, (2) empirical measurements, and (3) iterative design.

The first step defines the user group. The process of defining the user group was an iterative and sometimes painstaking process. OpTech researchers wanted to include as many disciplines and professional types as possible in the targeted user group; this was easy to do because TRAM touches on so many disciplines and subject areas. It includes aspects of toxicology, risk assessment, risk management, process/chemical engineering, human factors engineering, safety engineering, and pollution prevention; each a complete discipline in its own right. Each of the above diciplines tends to be an expert in his/her own area and is only generally cognizant of the other areas. Attempts to include these disciplines as user groups causes a geometric explosion of user information requirements. For instance, if the toxicologist happens to be the user, the system must augment (provide) him/her with stronger support in all the other areas in which he/she is not an expert. This defines one set of user support functions and information requirements. If the process engineer is also included as a user of the system, the same rationale applies and another set of user support functions and information requirements is created.

The tendency to try to include any discipline remotely related to risk assessment was solved by close examination of a straightforward question: "What is the problem we are trying to help solve, and who is solving that problem in the real world?" The problem was defined as "supporting and simplifying aspects of maintenance and manufacturing process design and evaluation with respect to chemical health and safety hazards as identified in regulatory requirements." "Who is performing these processes in the real world?" Through literature review and two in-depth interviews in Phase I, it was concluded that industrial hygiene engineers and process/chemical engineers are generally performing these functions. To a somehwhat lesser degree, human factor specialists are performing the function and are considered a viable part of the user group.

As part of Phase I, OpTech looked at the better-defined user group and the tasks it performs in assessing risk posed by chemical hazards in the workplace. In short, their tools and procedures included the use of process flow diagrams, materials mass balance, an understanding of the unit operations making up the process, mishap analysis (e.g., fault tree analysis), chemical data, regulatory requirements, and worker task analysis, all used for decision-making. The resulting user information requirements for performing these tasks should be assessed and integrated into early rapid prototyping of future work. Empirical testing with sample users will be conducted with early prototypes to better define true user and system requirements as well as the "look and feel" of the interface.

It is suggested that the TRAM system be developed as a Windows-based software program. The analysis environment should be highly iconic and graphical. Although the design and development of the specific TRAM interface is a complex and novel process, there are some very sound and proven interface design principles that can be used as guidelines and checklists throughout user-interface development. Truly good graphical user interface (GUI design guidelines) are based on sound human factors principles and tend to be platform-independent. One of the better set of design guidelines is published by Apple Computer, Inc. At a high level, the guidelines encompass the following rules-of-thumb of a graphical interface design and should be the basic principles used in designing and empirically evaluating the TRAM interface:

1. Use metaphors from the real world
2. Allow for direct manipulation
3. Provide for see-and-point interaction where possible
4. Ensure internal and external consistency
5. Implement WYSIWYG (what you see is what you get) approach
6. Give the user control over all actions
7. Provide feedback and dialogue
8. Provide a forgiving interface (reversible commands)
9. Ensure perceived stability (keep it understandable and familiar)
10. Provide aesthetic integrity

Source: (Apple Computer, Inc., 1987)

Interface development is a critical aspect of a software development project. However, the interface development plan should be incorporated into an integrated software development management plan. OpTech suggests a plan modeled after a technical report from the Software Technology Support Center, Ogden ALC/TISE, Hill AFB, UT 84056. The document, Software Management Guide, 1993, is a set of guidance documents aimed at improving the management process in software development projects. It includes guidance on all aspects of a software development program including total quality management (TQM), cost estimation, risk management, software design, development and reuse, test and evaluation, documentation, and more.

Noteworthy is the specific development approach that OpTech suggests in developing TRAM. The conventional development process is shown in Figure 13. This process was most often used in past DoD software acquisition efforts. It is often called the "waterfall" software life cycle because of the way it is drawn. The "waterfall" process begins with the definition of the system and software requirements, proceeds through design and coding phases, and concludes with increasingly comprehensive test activities. After system testing, the complete system is deployed and maintained. At the end of each activity or phase, reviews are held to ensure successful completion of that stage. This approach is consistent with pertinent requirements of DoD-STD-2167A, Defense System Software Development.

Several problems can arise when using the conventional or "waterfall" software development process in some situations. It may not be possible to define the software requirements fully at the beginning of the software development. The design approach created to satisfy the requirements may be inadequate. The user only receives the software at the end of the complete and lengthy process, at which time it is too late to integrate significant input. Other software development processes have been created to address situations where the software requirements can be completely defined at the start, where there is significant risk in the design approach, or where an early initial capability is needed. Two of these

alternatives include the evolutionary development process and the prototyping approach. Both alternatives can be overlaid onto the "waterfall" approach to software development.

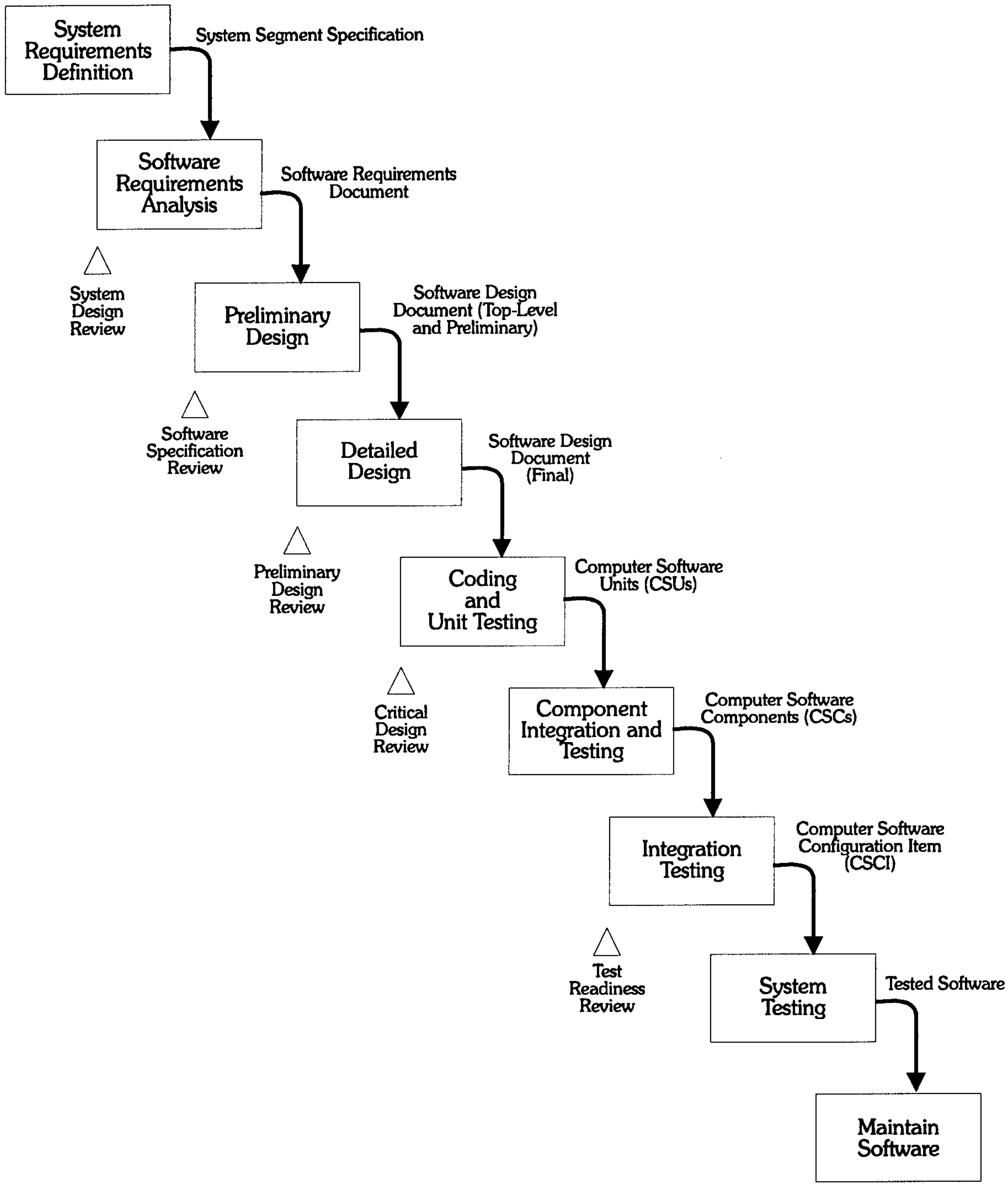


Figure 13. "Waterfall" Software Development Process

The evolutionary development process is an approach where the general system and software objectives are defined, the system architecture is selected, and an evolutionary development plan is developed. One increment, or portion of the system, that provides a useful portion of the total systems capabilities

is designed, coded, and tested. The increment is presented to the user for evaluation, and in some cases actual operation. The results of this evaluation are then used to select, design, code, and test the next increment. This process is repeated until the software is completely developed.

In the prototyping approach, the most important and critical software requirements are defined to the extent that current knowledge and experience permit. A "quick" design addressing these requirements is prepared, and a rapid prototype is coded and tested. The purpose of the prototype is to gain information about the total requirements and confidence in the correctness of the design approach; characteristics needed in the final software product such as efficiency, maintainability, capacity, and adaptability might be ignored in the prototype. The prototype is evaluated, preferably with extensive user participation, to refine the initial requirements and design. After confidence in the requirements and design approach is achieved, the final software is developed using a process similar to the "waterfall" approach. The prototype might be discarded, or a portion of it might be used to develop the final product.

In the development of the TRAM, OpTech suggests the basic "waterfall" process integrated with aspects of both the evolutionary and prototyping approaches. The evolutionary approach is attractive because the TRAM is a significantly large software project and this approach provides a method for breaking the problem into manageable steps. For instance, the exposure assessment function is one incremental step that can be developed and tested prior to moving on to the risk management function. Prior completion of the exposure assessment function should contribute to the quality of the risk management function. Other incremental functions include hazard identification, pollution prevention opportunities, graphical analysis environment, and documentation and reporting. However, OpTech believes that there is also a need to provide the user evaluating the incremental portion of the system with the overall context of TRAM. To accomplish this, rapid prototypes of the entire system, with sufficient fidelity to provide the user with the current gestalt of the entire TRAM system, should be developed. This would allow designers to maintain a proof of concept with potential users as they are evaluating incremental portions of the system. The "waterfall" approach, modified for the specific characteristics of TRAM development, should prove to be an effective implementation and management strategy.

C.3. System Test and Evaluation

Figure 14 illustrates the general TRAM system development flow to include integrated system test and evaluation. This is an iterative approach found in object-oriented design (Booch, 1991) and involves analysis, design, evolution, and modification. This is not equivalent to the traditional waterfall software development life cycle shown in Figure 13 because it utilizes an incremental, iterative process. The objective would be to retain the good management practices learned from the experience of the waterfall life cycle but, at the same time, acquire evolutionary development via rapid prototyping and the appropriate use of software development tools.

C.4. Commercialization Potential Report

Under the SBIR program, commercial feasibility must be considered as well as technical feasibility. A commercialization potential report is included here to address this need.

(1) Possible technology applications (military and/or other government). TRAM is a software package that would operate under Windows. It would allow the simulation of industrial processes with the purpose of estimating worker risk to chemical and physical hazards associated with that process. This is of particular interest to the maintenance operations associated with large-scale weapon systems found in the DoD. This tool would be useful from an engineering design viewpoint because alternate designs

can be compared with respect to risk and cost. It would also be a good tool for assessment of existing maintenance processes since it can capture the process via simulation, thus assisting with identification of problem areas and development of cost-effective system upgrades.

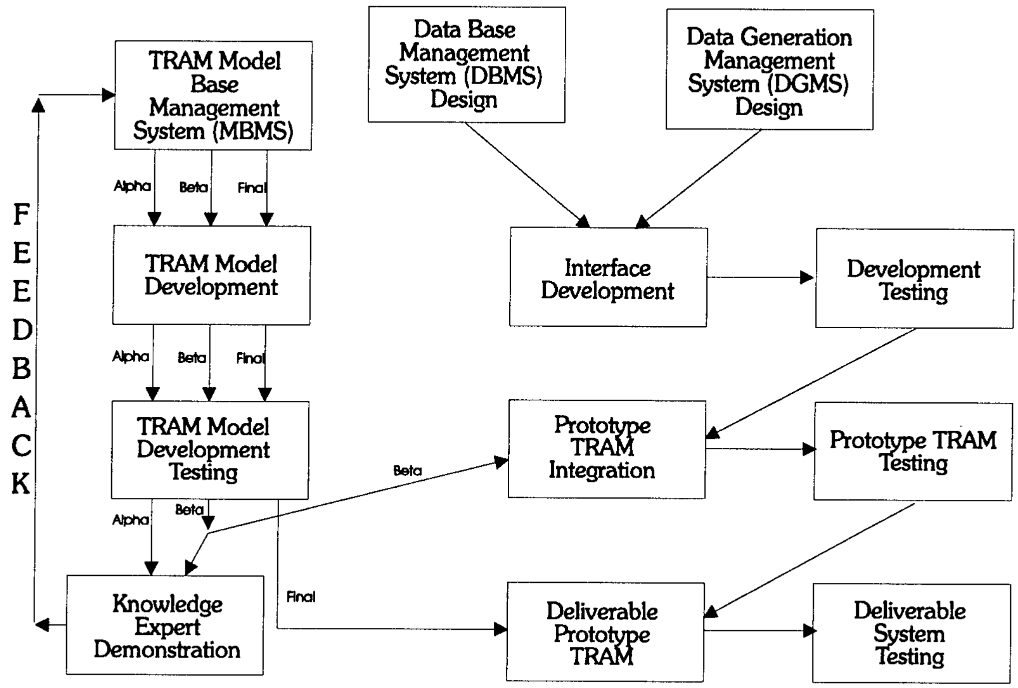


Figure 14. TRAM System Development and Testing

(2) Possible technology applications (private sector). TRAM would be just as applicable to private industry maintenance operations as it is to DoD facilities. Additionally, since the package would allow the simulation of processes composed of a wide number of unit operations, it will also have value in industry for estimating worker risk associated with manufacturing operations. Another private sector application is as a training device for industrial hygienists, human factor specialists, and process engineers (secondarily) in the occupational health and safety aspects of manufacturing and/or maintenance operations.

(3) Customer feedback on selected applications (military/federal). The feedback from individuals within the government, so far, has been favorable concerning the conceptual approach taken by OpTech to develop TRAM. It is clear that the need for such a tool exists. One excellent form of feedback from an Army toxicologist, who is also an industrial hygienist, was referral to an excellent workplace epidemiological study (Copeland, 1994) done at Hill AFB. This study, along with other studies, will substantially help with the development (e.g., reality checks) and/or validation of TRAM's performance. Though no formal feedback from governmental organizations, per se, has been obtained (it is really too early for that), several professionals (human factors, toxicologists, industrial hygienists) have provided encouraging feedback.

(4) Customer feedback on selected applications (private sector). Feedback from the private sector has been fairly strong and favorable. This was clearly documented by the letters of commitment from our industry partners. These companies feel strongly that TRAM will meet definite industry needs for linking health risk analysis with task analysis such that methodical task-based risk assessment and subsequent risk management can be achieved in a cost-effective manner. OpTech expects that the feedback from potential customers will be more definitive as the operational features of TRAM can be demonstrated at selected points in future development.

(5) Selected commercialization factors. OpTech has been assessing the commercialization potential of TRAM even before the Phase I proposal was written. Toward the end of the six-month project, however, the effort has intensified and the process has become more structured.

A recent study by OpTech (Harrah et al., 1993) addressed the management of an R&D investment portfolio. One useful conceptual scheme (Souder and Bethay, 1993) reviewed as part of that study, is the risk pyramid for new product development. Figures 15 and 16 illustrate the concept, which is proving to be quite useful in the current evaluation of TRAM. The model is useful for addressing the conventional attributes of a commercialization potential assessment.

The basic paradigm, a product concept triangle, is presented in Figure 15. It shows that **technology** is used to create product **form** that produces **benefits** for some customers. This figure makes it clear that maintaining a balance among technology, form, and benefits is the key to success. For example, as depicted by the broken lines in Figure 15, if the technology side of the triangle is extended (e.g., the technology gets too "high") while the form and benefits stay the same, then product failure may be imminent (the concept falls off the triangle). Early laser products are an example. It was not until laser technology was reduced to a less exotic state and product engineering capabilities (the capability to design useful forms of the product) were developed during the 1980s that a viable product concept could be supported. A similar imbalance can occur on the other side of the triangle if the form side is too long (e.g., product form too complex). Remote-controlled mining technologies of the 1950s are an example. The basic technologies were uncomplicated, but the engineered forms of the products were impossibly complex for most mining environments. In general, the entire triangle may topple if its base is too narrow relative to its height; for example, a high-technology product with complex form that lacks commercial benefits. But note that a very short triangle with an excessively wide base (many benefits but low form and technology) may collapse under a weighty product concept. Japanese autos of the 1950s are an example. Designed to include many features (heavy concept), their technologies and forms were inadequate to achieve a reliable product. Thus, the lengths of the sides of the triangle and the size of the concept must all be consistent in order to maximize the likelihood of product success. Figure 15 must not be interpreted as implying that the three sides of the triangle are always independent. Technology usually leads to form, which leads to benefits. However, the sides of the triangle are usually not linearly dependent, and many variations of the technology (different lengths of the technology side of the triangle) may be possible with the same form and benefits. Thus, there is considerable decision-making latitude in optimizing cost-performance trade-offs. In general, it can be expected that any change in one side of the triangle will induce some changes in one or more of the remaining sides. The product triangle concept is very useful in focusing discussion and encouraging productive debates between members of the research team and, also, managers.

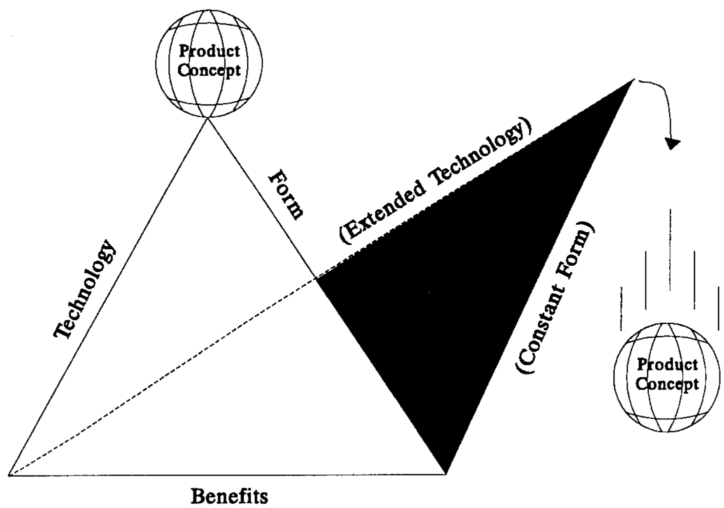


Figure 15. Product Concept Triangle

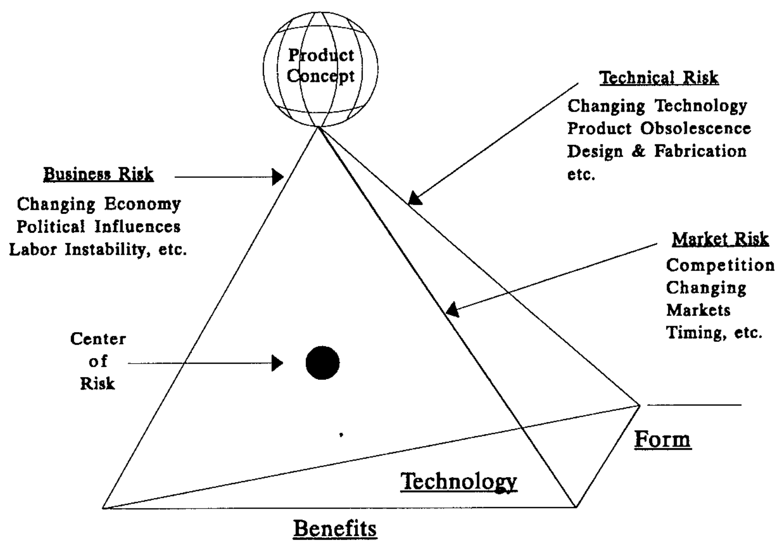


Figure 16. Risk Pyramid Paradigm

An important extension of the product concept triangle is shown in Figure 16. It extends the notions to include **risk** (e.g., potential for loss or harm to the developer). Three types of risks are considered in this figure: technical, market, and business risk. **Technical risk** refers to the potential for loss or harm from events related to the technology, its design, or its manufacture. **Market risk** refers to the potential for harm due to competitive actions and reactions, changing market needs, new user requirements, or other market factors. **Business risk** refers to the harm that can occur from political, economic, labor, or other factors within the business environment. The labeling of the edges in Figure 16 is not arbitrary, although they may be labeled differently than shown here, depending on the user's intent. We found the model to be most useful and logical when **the product triangle is labeled as the base of the pyramid**, and the three risk axes are positioned relative to the technology, form, and benefits axes as shown. In this way, changes in business and market risks are most closely tied to changes in benefits. Changes in market and technical risks are most closely tied to changes in the product form, and changes in business and technical risks are most closely tied to changes in the

technology (Souder & Bethay, 1993). Thus, the pyramid can be used to depict many complex interactions among the three risks, the technology, the form, and the benefits of the product. The following text considers these factors with respect to the future development of TRAM.

Technology. The technology attribute for TRAM, as a new product, is not a barrier to successful commercialization. Even though TRAM would incorporate a fuzzy knowledge base that draws upon the principles and technological advances made in the area of fuzzy logic, it can be implemented on a very conventional platform (e.g., under Microsoft Windows on a typical personal computer). Development tools will be used to allow cost-effective coding of the design. With respect to technology, the most negative factor may well be that frequently faced by innovative tools and/or methods; that is, there will be some degree of "resistance" by people who believe that only classical techniques should be used. TRAM utilizes a blend of fuzzy and classical techniques. This "mixing" of methods (driven mainly by the precision in the utilized information) emphasizes that fuzzy methods are intended to augment the arsenal of classical techniques available, as opposed to being a generally competing method.

Form. The form attribute of TRAM should enhance the commercialization since it is an easily engineered form which is familiar to most potential customers. TRAM would be operated on a PC platform under a Windows environment. The user interface will be friendly, in many cases prompting for inputs in natural language, and, as appropriate, provide default values for variables and parameters to assist the user setup of the simulation needed to estimate task-based worker risk.

Benefits. TRAM would benefit the user in some very fundamental ways. It would allow worker risk to chemical hazards to be estimated in the realistic context of task performance and would suggest risk management actions that may be taken to maneuver the risk level into an acceptable range. TRAM would be applicable to the assessment of existing workplaces and to the design of future workplaces. Select report-writing features would be provided to assist with the development and maintenance of job exposure profiles and to enhance occupational health programs. The benefits are substantial considering the sensitivity of society to the exposure of workers to chemical hazards in the performance of their duties.

Technical Risk. Consideration of the technical risk associated with TRAM requires an assessment of the embedded fuzzy logic technology. As an enabling technology, fuzzy logic could open new vistas for the computer software and hardware industries. Researchers in fuzzy logic are recognizing that combining this technology with AI rule-based systems provides an ideal test bed for the development of very high performance computers. Particularly, fuzzy logic's expressive power in using natural language and generalizations could enable it to contribute to the development of the next generation of computers (U.S. Department of Commerce, 1991).

For manufacturing companies, fuzzy control systems could strengthen their industrial processing methods and create competitive products. Several fuzzy logic experts have expressed their opinion that although fuzzy logic control is now the most popular application of fuzzy theory, other applications such as pattern recognition and image processing will soon emerge. This accelerating use of fuzzy logic in industrial process control would provide a basis for the technical acceptance of TRAM, which would provide a basis for workplace risk by using similar fuzzy techniques.

Fuzzy logic development tools and shells should open new application frontiers. Fuzzy logic has been incorporated into the development of fuzzy chips and spinoffs, like neural networks/fuzzy logic chips. To run more complex fuzzy logic solutions, there will be a constant push for more processor power

and speed. Several companies, like Togai InfraLogic in Irvine, California, and Aptronix, Inc., in San Jose, California, are offering dedicated fuzzy logic processors.

Business Risk. In terms of business environment, the increasing regulatory pressure to protect the health of workers (as well as the ecology) is conducive to effective tools, methods and techniques for human health risk and management. In this context, consider the OSHA PSM standard discussed earlier. The prime objective of the OSHA PSM standard is to prevent unwanted releases of hazardous chemicals, especially into locations that would expose employees and others to serious hazards. The actions to be taken as specified by the standard are ideally supported by TRAM, particularly the PHA. This standard should reduce product risk if TRAM is in tune with the requirements of the standard. In fact, the PSM standard can be compared to the Hazard Communication (HAZCOM) standard. For instance, when HAZCOM was first implemented, organizations scrambled to meet the requirements. As a result of implementing too quickly, and from possible neglect or ignorance of the standard, many of the developed HAZCOM programs were substandard. It is only recently that many companies are developing well designed and thorough HAZCOM programs. The same could be true with the PSM standard. It was enacted in 1992 and has a five-year phase-in plan. By the end of the five-year plan, the required **PHA** must be implemented. Efforts to develop and execute PHA will certainly peak around 1997, however, they will still be required in years beyond 1997. TRAM, if development continues, should be completed in approximately March 1997. The timing may be ideal from a product development and marketing point of view because the product would be complete by the end of the five-year phase-in for the PSM standard. There should not be time for competitive products to be ready for use since our extensive literature searches indicated no competitive products exist or are currently under advanced development.

Fuzzy logic as a commercial opportunity is extremely promising. There are several U.S. government agencies funding research in the fuzzy logic area. Companies such as General Electric, Ford, United Technologies, Honeywell, and Rockwell International are investing in the R&D of fuzzy logic technology for use in their products. Some industry representatives have indicated that their companies are already experiencing the cost effectiveness of fuzzy-logic-based products. **All of these factors create a business environment conducive to innovative technologies such as TRAM which utilize fuzzy methods as an approach for handling complex problems.**

Market Risk. The market for TRAM is, in many respects, an emerging market because (1) it is being stimulated by strengthening regulatory drivers and (2) the fuzzy logic technology to be utilized in TRAM is, itself, relatively new. The ability of TRAM to handle the imprecise information inherently associated with worker health risk assessment would place it at an advantage over the most likely classical approaches by competitors in the environmental and occupational health/safety software industry. Finally, (3) TRAM would integrate task analysis with exposure analysis, an approach not taken in currently available software.

Meanwhile, the rapidly expanding market for fuzzy logic applications in new products will certainly elevate the "awareness level" of competitors regarding the advantages of using fuzzy technologies in task-based risk assessment software. Therefore, timing is an important factor.

With respect to competition, OpTech is in good position at this time. However, Japan, with its strong background in commercialization of fuzzy logic products in systems control applications, is moving in the direction of other application areas to include information systems. This is the general area of science in which TRAM is located (e.g., decision support in the interdisciplinary areas of human factors and occupational health).

At this point, assessment of TRAM indicates that it is a feasible technology with a significant payoff to both the DoD and to commercial customers. It would be expected to successfully penetrate the expanding health and safety software market, with particular benefit to the maintenance industry and quite likely to manufacturing (since both can be characterized via sequences of unit operations). The inclusion of fuzzy methods would allow the handling of imprecise attributes commonly found in workplace risk assessment and management, especially at the systems design stage where alternative designs are evaluated without direct measurements. From a marketing viewpoint, it should also be noted that successful development of TRAM paves a way for follow-on products that address worker risks associated with physical agents (e.g., lasers, ionizing radiation, and radio frequency). The conceptual technology framework established in the TRAM system should accelerate these developments.

(6) Commercialization Schedule. It was determined in Phase I that, for a number of reasons, it was not advantageous to establish a full commercialization plan. Barriers included a tight schedule, uncertainty level associated with downstream technology development, and intellectual property ownership. It was concluded that the midst of a Phase I feasibility study is not an advantageous position to gain actual commitments to Phase II or Phase III funding from other parties. It is likely, in our opinion, that to get commitments at this early stage without significant contingencies would require OpTech to essentially "sell the farm." With a product having the high potential of TRAM, we decided on an approach that allows the commercialization issues to be accomplished in a phased manner, with the phasing linked to the technology development phases. In this manner, agreements concerning equity, financing, marketing, and licensing can be "shaped" as the TRAM technology matures in Phase II and Phase III and the information basis for decision-making is enhanced. This approach is patterned after a strategy presented in a DoD SBIR workshop conducted by Dawnbreaker (Dawnbreaker Press, 1994).

A strong indicator of the high commercialization potential of the TRAM system is the industry partnering relationship OpTech has been able to negotiate at this early stage of development. As illustrated in Figure 17 and documented by letters of commitment, a form of teaming arrangement has been put in place to significantly increase the odds of successful commercialization of TRAM. Micro Analysis and Design will primarily provide technical support via the integration of its Micro Saint simulation software (queuing model) into TRAM. Another small high-technology firm was identified that has strong ties to the electric power industry (including formal recognition for outstanding research for the Electric Power Research Institute), having developed and sold significant process software to that industry. Consequently, OpTech determined that the power industry would be an excellent initial industrial market segment. This company's financial and technical contributions to Phase III would be determined by TRAM system test results late in Phase II. A third company, a venture capital firm, has a strong interest in the commercialization of TRAM. The degree and exact terms of its support will be addressed in a staged fashion throughout development as technical progress occurs. OpTech has the appropriate partnering arrangement in place to ensure maximum commercialization potential for the TRAM technology.

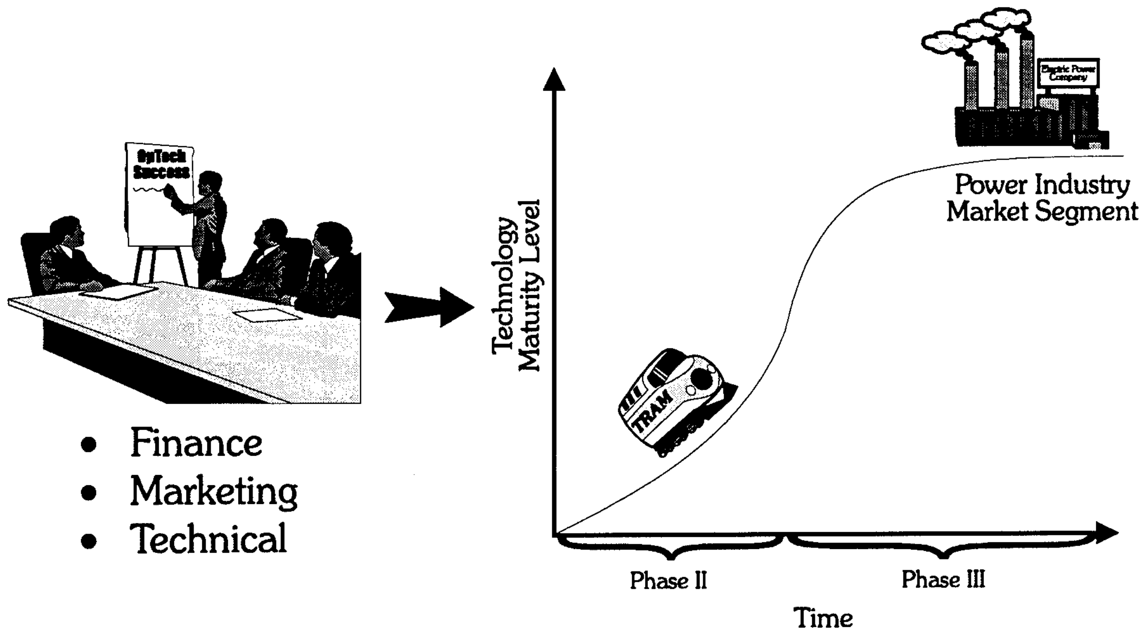


Figure 17. Successful Commercialization of TRAM

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